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code of federal regulations

Food and Drugs

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21

PARTS 170 TO 199
Revised as of April 1, 1987

869-002-00061-5

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Food and Drugs

21

PARTS 170 TO 199

Revised as of April 1, 1987

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AS OF APRIL 1, 1987

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To cite the regulations in this volume use title, part and section number. Thus, 21 CFR 170.3 *refers to Title 21, Part 170, section 3.*

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

ISSUE DATES

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16	as of January 1
Title 17 through Title 27	as of April 1
Title 28 through Title 41	as of July 1
Title 42 through Title 50	as of October 1

The appropriate revision date is printed on the cover of each volume.

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The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to display an OMB control number with their information collection request. Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

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What is incorporation by reference? Incorporation by reference was established by statute and allows Federal agencies to meet the requirement to publish regulations in the Federal Register by referring to materials already published elsewhere. For an incorporation to be valid, the Director of the Federal Register must approve it. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register (5 U.S.C. 552(a)). This material, like any other properly issued regulation, has the force of law.

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(a) The incorporation will substantially reduce the volume of material published in the Federal Register.

(b) The matter incorporated is in fact available to the extent necessary to afford fairness and uniformity in the administrative process.

(c) The incorporating document is drafted and submitted for publication in accordance with 1 CFR Part 51.

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III). A list of CFR Titles, Chapters, and Parts and an alphabetical list of agencies publishing in the CFR are also included in this volume.

An index to the text of "Title 3—The President" is carried within that volume.

The Federal Register Index is issued monthly in cumulative form. This index is based on a consolidation of the "Contents" entries in the daily Federal Register.

A List of CFR Sections Affected (LSA) is published monthly, keyed to the revision dates of the 50 CFR titles.

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For a summary, legal interpretation, or other explanation of any regulation in this volume, contact the issuing agency. Inquiries concerning editing procedures and reference assistance with respect to the Code of Federal Regulations may be addressed to the Director, Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408 (telephone 202-523-3517). Sales are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402 (telephone 202-783-3238).

John E. Byrne,
Director,
Office of the Federal Register.

April 1, 1987.

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THIS TITLE

Title 21—Food and Drugs is composed of nine volumes. The parts in these volumes are arranged in the following order: Parts 1-99, 100-169, 170-199, 200-299, 300-499, 500-599, 600-799, 800-1299, and 1300-End. The first eight volumes, containing Parts 1-1299, comprise Chapter I—Food and Drug Administration, Department of Health and Human Services. The ninth volume, containing Part 1300 to End, includes Chapter II—Drug Enforcement Administration, Department of Justice. The contents of these volumes represent all current regulations codified under this title of the CFR as of April 1, 1987.

The Table of Excepted Prescription Drugs to Part 1308 appears in the volume containing Part 1300-End.

Redesignation tables for Chapter I—Food and Drug Administration appear in the Finding Aids section of the first eight volumes.

For this volume, Janice E. Booker was Chief Editor. The Code of Federal Regulations publication program is under the direction of Martha B. Girard, assisted by Robert E. Jordan.

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Title 21—Food and Drugs

(This book contains Parts 170 to 199)

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CHAPTER I—Food and Drug Administration, Department of Health and Human Services (Continued)..................................... 170

CROSS REFERENCES: Food Safety and Inspection Service, Department of Agriculture: See Meat and Poultry Inspection, 9 CFR Chapter III.

Federal Trade Commission: See Commercial Practices, 16 CFR Chapter I.

United States Customs Service, Department of the Treasury: See Customs Duties, 19 CFR Chapter I.

Internal Revenue Service, Department of the Treasury: See Internal Revenue, 26 CFR Chapter I.

Bureau of Alcohol, Tobacco, and Firearms, Department of the Treasury: See Alcohol, Tobacco Products and Firearms, 27 CFR Chapter I.

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CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Continued)

(Parts 170 to 199)

EDITORIAL NOTES: 1. Nomenclature changes affecting this Chapter appear at 45 FR 40976, June 17, 1980 and 46 FR 8454, Jan. 27, 1981.

2. The Food and Drug Administration published a document at 49 FR 41019, Oct. 19, 1984 establishing July 1, 1987, as a uniform effective date for compliance for regulations affecting the labeling of food products. At 51 FR 34085, Sept. 25, 1986, FDA established January 1, 1989 as a new uniform effective date for compliance. The new uniform effective date will apply only to final FDA food labeling regulations published after July 1, 1986, and before January 1, 1988.

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PART 170—FOOD ADDITIVES

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170.6 Opinion letters on food additive status.
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170.45 Fluorine-containing compounds.
170.50 Glycine (aminoacetic acid) in food for human consumption.
170.60 Nitrites and/or nitrates in curing premixes.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

SOURCE: 42 FR 14483, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 170.3 Definitions.

For the purposes of this subchapter, the following definitions apply:

(a) "Secretary" means the Secretary of Health and Human Services.

(b) "Department" means the Department of Health and Human Services.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301-392).

(e) "Food additives" includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. "Affecting the characteristics of food" does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) "Common use in food" means a substantial history of consumption of a substance by a significant number of consumers in the United States.

(g) The word "substance" in the definition of the term "food additive" includes a food or food component consisting of one or more ingredients.

(h) "Scientific procedures" include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

(i) "Safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

(j) The term "nonperishable processed food" means any processed food not subject to rapid decay or deterioration that would render it unfit for consumption. Examples are flour, sugar, cereals, packaged cookies, and crackers. Not included are hermetically sealed foods or manufactured dairy products and other processed foods requiring refrigeration.

(k) "General recognition of safety" shall be determined in accordance with § 170.30.

(l) "Prior sanction" means an explicit approval granted with respect to use of a substance in food prior to September 6, 1958, by the Food and Drug Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(m) "Food" includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

(n) The following general food categories are established to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. Individual food products will be included within these categories according to the detailed classifications lists contained in Exhibit 33B of the report of the National Academy of Sciences/National Research Council report, "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22151, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408:

(1) Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.

(2) Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.

(3) Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.

(4) Breakfast cereals, including ready-to-eat and instant and regular hot cereals.

(5) Cheeses, including curd and whey cheeses, cream, natural, grating, processed, spread, dip, and miscellaneous cheeses.

(6) Chewing gum, including all forms.

(7) Coffee and tea, including regular, decaffeinated, and instant types.

(8) Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.

(9) Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.

(10) Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.

(11) Egg products, including liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs.

(12) Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.

(13) Fish products, including all prepared main dishes, salads, appetizers, frozen multicourse meals, and spreads containing fish, shellfish, and other aquatic animals, but not fresh fish.

(14) Fresh eggs, including cooked eggs and egg dishes made only from fresh shell eggs.

(15) Fresh fish, including only fresh and frozen fish, shellfish, and other aquatic animals.

(16) Fresh fruits and fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared "ades" and punches made therefrom.

(17) Fresh meats, including only fresh or home-frozen beef or veal, pork, lamb or mutton and home-prepared fresh meat-containing dishes, salads, appetizers, or sandwich spreads made therefrom.

(18) Fresh poultry, including only fresh or home-frozen poultry and game birds and home-prepared fresh poultry-containing dishes, salads, appetizers, or sandwich spreads made therefrom.

(19) Fresh vegetables, tomatoes, and potatoes, including only fresh and home-prepared vegetables.

(20) Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.

(21) Fruit and water ices, including all frozen fruit and water ices.

(22) Gelatins, puddings, and fillings, including flavored gelatin desserts, puddings, custards, parfaits, pie fillings, and gelatin base salads.

(23) Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.

(24) Gravies and sauces, including all meat sauces and gravies, and tomato, milk, buttery, and specialty sauces.

(25) Hard candy and cough drops, including all hard type candies.

(26) Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.

(27) Jams and jellies, home-prepared, including only home-prepared jams, jellies, fruit butters, preserves, and sweet spreads.

(28) Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.

(29) Meat products, including all meats and meat containing dishes, salads, appetizers, frozen multicourse meat meals, and sandwich ingredients prepared by commercial processing or using commercially processed meats with home preparation.

(30) Milk, whole and skim, including only whole, lowfat, and skim fluid milks.

(31) Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.

(32) Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.

(33) Plant protein products, including the National Academy of Sciences/National Research Council "reconstituted vegetable protein" category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.

(34) Poultry products, including all poultry and poultry-containing dishes, salads, appetizers, frozen multicourse poultry meals, and sandwich ingredients prepared by commercial processing or using commercially processed poultry with home preparation.

(35) Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, "-ades", and drink substitutes made therefrom.

(36) Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.

(37) Snack foods, including chips, pretzels, and other novelty snacks.

(38) Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.

(39) Soups, home-prepared, including meat, fish, poultry, vegetable, and combination home-prepared soups.

(40) Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes.

(41) Sugar, white, granulated, including only white granulated sugar.

(42) Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.

(43) Sweet sauces, toppings, and syrups, including chocolate, berry,

fruit, corn syrup, and maple sweet sauces and toppings.

(o) The following terms describe the physical or technical functional effects for which direct human food ingredients may be added to foods. They are adopted from the National Academy of Sciences/National Research Council national survey of food industries, reported to the Food and Drug Administration under the contract title "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22151, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, D.C. 20408:

(1) "Anticaking agents and free-flow agents": Substances added to finely powdered or crystalline food products to prevent caking, lumping, or agglomeration.

(2) "Antimicrobial agents": Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under "preservatives."

(3) "Antioxidants": Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.

(4) "Colors and coloring adjuncts": Substances used to impart, preserve, or enhance the color or shading of a food, including color stabilizers, color fixatives, color-retention agents, etc.

(5) "Curing and pickling agents": Substances imparting a unique flavor and/or color to a food, usually producing an increase in shelf life stability.

(6) "Dough strengtheners": Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of Sciences/National Research Council under "dough conditioner."

(7) "Drying agents": Substances with moisture-absorbing ability, used to maintain an environment of low moisture.

(8) "Emulsifiers and emulsifier salts": Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

(9) "Enzymes": Enzymes used to improve food processing and the quality of the finished food.

(10) "Firming agents": Substances added to precipitate residual pectin, thus strengthening the supporting tissue and preventing its collapse during processing.

(11) "Flavor enhancers": Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.

(12) "Flavoring agents and adjuvants": Substances added to impart or help impart a taste or aroma in food.

(13) "Flour treating agents": Substances added to milled flour, at the mill, to improve its color and/or baking qualities, including bleaching and maturing agents.

(14) "Formulation aids": Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

(15) "Fumigants": Volatile substances used for controlling insects or pests.

(16) "Humectants": Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and antidusting agents.

(17) "Leavening agents": Substances used to produce or stimulate production of carbon dioxide in baked goods to impart a light texture, including yeast, yeast foods, and calcium salts listed by the National Academy of Sciences/National Research Council under "dough conditioners."

(18) "Lubricants and release agents": Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.

(19) "Non-nutritive sweeteners": Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(20) "Nutrient supplements": Substances which are necessary for the

body's nutritional and metabolic processes.

(21) "Nutritive sweeteners": Substances having greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(22) "Oxidizing and reducing agents": Substances which chemically oxidize or reduce another food ingredient, thereby producing a more stable product, including the applicable effect listed by the National Academy of Sciences/National Research Council under "dough conditioners."

(23) "pH control agents": Substances added to change or maintain active acidity or basicity, including buffers, acids, alkalies, and neutralizing agents.

(24) "Processing aids": Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc.

(25) "Propellants, aerating agents, and gases": Gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.

(26) "Sequestrants": Substances which combine with polyvalent metal ions to form a soluble metal complex, to improve the quality and stability of products.

(27) "Solvents and vehicles": Substances used to extract or dissolve another substance.

(28) "Stabilizers and thickeners": Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

(29) "Surface-active agents": Substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.

(30) "Surface-finishing agents": Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings.

(31) "Synergists": Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) "Texturizers": Substances which affect the appearance or feel of the food.

[42 FR 14483, Mar. 15, 1977, as amended at 47 FR 11835, Mar. 19, 1982]

§ 170.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquiries as to the safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Pub. L. 85-929; Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health".

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

(1) Is a food additive within the meaning of section 201(s) of the act; or

(2) Is generally recognized as safe (GRAS); or

(3) Has prior sanction or approval under that amendment; or

(4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health and Human Services, Food and Drug Administration, Bureau of Foods, 200 C Street SW., Washington, DC 20204, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration to be food additives nor to articles included in regulations in Parts 170 through 189 of this chapter if the articles are used in accordance with the requirements of such regulations.

(Sec. 201, 72 Stat. 1784-88, as amended; 21 U.S.C. 321)

§ 170.10 Food additives in standardized foods.

(a) The inclusion of food ingredients in Parts 170 through 189 of this chapter does not imply that these ingredients may be used in standardized foods unless they are recognized as optional ingredients in applicable food standards. Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the Act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the Act requires that the Secretary publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(c) A regulation will not be issued allowing the use of a food additive in a food for which a definition and standard of identity is established, unless its issuance is in conformity with section 401 of the Act or with the terms of a temporary permit issued under § 130.17 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the food additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

§ 170.15 Adoption of regulation on initiative of Commissioner.

(a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the FEDERAL REGISTER and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall proceed as provided in Part 10 of this chapter.

[42 FR 14486, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

§ 170.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

A food additive or food containing a food additive intended for investigational use by qualified experts shall be exempt from the requirements of section 409 of the Act under the following conditions:

(a) If intended for investigational use in vitro or in laboratory research animals, it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(b) If intended for use in animals other than laboratory research animals and if the edible products of the animals are to be marketed as food, permission for the marketing of the edible products as food has been requested by the sponsor, and authorization has been granted by the Food and Drug Administration in accordance with § 511.1 of this chapter or by the Department of Agriculture in accordance with 9 CFR 309.17, and it bears a label which states prominently, in addition to the other information required by the Act, the warning:

Caution. Contains a new food additive for use only in investigational animals. Not for use in humans.

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

(c) If intended for nonclinical laboratory studies in food-producing animals, the study is conducted in compliance with the regulations set forth in Part 58 of this chapter.

[42 FR 14483, Mar. 15, 1977, as amended at 43 FR 60021, Dec. 22, 1978]

§ 170.18 Tolerances for related food additives.

(a) Food additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives.

(b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present or unless it is shown that a higher tolerance is reasonably required for the combined additives to accomplish the physical or technical effect for which such combined additives are intended and that the higher tolerance will be safe.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(1) Determine the quantity of each residue present.

(2) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.

(3) Add the percentages so obtained for all residues present.

(4) The sum of the percentage shall not exceed 100 percent.

§ 170.19 Pesticide chemicals in processed foods.

When pesticide chemical residues occur in processed foods due to the use of raw agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the Act, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed in removing any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food when ready to eat is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the Act. For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. Food that is itself ready to eat, and which contains a higher residue than allowed for the raw agricultural commodity, may not be legalized by blending or mixing with other foods to reduce the residue in the mixed food below the tolerance prescribed for the raw agricultural commodity.

Subpart B—Food Additive Safety

§ 170.20 General principles for evaluating the safety of food additives.

(a) In reaching a decision on any petition filed under section 409 of the Act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferrable. For the purposes of this section, the principles for evaluating safety of additives set forth in the abovementioned publications will apply to any substance that may properly be classified as a food additive as defined in section 201(s) of the Act.

(b) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 170.22 Safety factors to be considered.

In accordance with section 409(c)(5)(C) of the Act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(c) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(d) The food ingredients listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in Part 182, Part 184 or § 186.1 of this chapter.

(e) Food ingredients were listed as GRAS in Part 182 of this chapter during 1958-1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in Part 184 or § 186.1 of this chapter.

(f) The status of the following food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to § 170.35, § 170.38, or § 180.1 of this chapter:

(1) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, and which has been modified by processes first introduced into commercial use after January 1, 1958, which may reasonably be expected significantly to alter the composition of the substance.

(2) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, that has had significant alteration of composition by breeding or selection after January 1, 1958, where the change may be reasonably expected to alter the nutritive value or the concentration of toxic constituents.

(3) Distillates, isolates, extracts, and concentration of extracts of GRAS substances.

(4) Reaction products of GRAS substances.

(5) Substances not of a natural biological origin, including those for which evidence is offered that they are identical to a GRAS counterpart of natural biological origin.

(6) Substances of natural biological origin intended for consumption for other than their nutrient properties.

(g) A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

(h) A food ingredient that is listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

(1) It complies with any applicable food grade specifications of the Food Chemicals Codex 2d Ed. (1972), or, if specifically indicated in the GRAS affirmation regulation, the Food Chemicals Codex, 3d Ed. (1981), which are incorporated by reference, except that any substance used as a component of articles that contact food and affirmed as GRAS in § 186.1 of this chapter shall comply with the specifications therein, or in the absence of such specifications, shall be of a purity suitable for its intended use. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) It performs an appropriate function in the food or food-contact article in which it is used.

(3) It is used at a level no higher than necessary to achieve its intended purpose in that food or, if used as a component of a food-contact article, at a level no higher than necessary to achieve its intended purpose in that article.

(i) If a substance is affirmed as GRAS in Part 184 or § 186.1 of this chapter with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(j) If an ingredient is affirmed as GRAS in Part 184 or § 186.1 of this chapter with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(k) Pursuant to § 170.35, a food ingredient may be affirmed as GRAS in Part 184 or § 186.1 of this chapter for a specific use(s) without a general evaluation of use of the ingredient. In addition to the use(s) specified in the regulation, other uses of such an ingredient may also be GRAS. Any affirmation of GRAS status for a specific use(s), without a general evaluation of use of the ingredient, is subject to reconsideration upon such evaluation.

(l) New information may at any time require reconsideration of the GRAS status of a food ingredient. Any change in Part 182, Part 184, or § 186.1 of this chapter shall be accomplished pursuant to § 170.38.

[42 FR 14483, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, either on his initiative or on the petition of an interested person, may affirm the GRAS status of substances that directly or indirectly become components of food.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS, he will place all of the data and information on which he relies on public file in the office of the Dockets Management Branch and will publish in the FEDERAL REGISTER a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS as described in § 170.30, he will publish a notice in the FEDERAL REGISTER listing the substance as GRAS in Part 182, Part 184, or Part 186 of this chapter, as appropriate.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the Act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 170.38.

(c)(1) Persons seeking the affirmation of GRAS status of substances as provided for in § 170.30(e), except those subject to the NAS-NRC GRAS list survey (36 FR 20546), shall submit a petition for GRAS affirmation pursuant to Part 10 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in § 170.30(b) have been met, in the following form:

(i) Description of the substance, including:

(*a*) Common or usual name.

(*b*) Chemical name.

(*c*) Chemical Abstract Service (CAS) registry number.

(*d*) Empirical formula.

(*e*) Structural formula.

(*f*) Specifications for food grade material, including arsenic and heavy metals. (Recommendation for any change in the Food Chemicals Codex monograph should be included where applicable.)

(*g*) Quantitative compositions.

(*h*) Manufacturing process (excluding any trade secrets).

(ii) Use of the substance, including:

(*a*) Date when use began.

(*b*) Information and reports or other data on past uses in food.

(*c*) Foods in which used, and levels of use in such foods, and for what purposes.

(iii) Methods for detecting the substance in food, including:

(*a*) References to qualitative and quantitative methods for determining the substance(s) in food, including the type of analytical procedures used.

(*b*) Sensitivity and reproducibility of such method(s).

(iv) Information to establish the safety and functionality of the substance in food. Published scientific literature, evidence that the substance is identical to a GRAS counterpart of natural biological origin, and other data may be submitted to support safety. Any adverse information or consumer complaints shall be included. Complete bibliographic references shall be provided where a copy of the article is not provided.

(v) A statement signed by the person responsible for the petition that to the best of his knowledge it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the safety and functionality of the substance.

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(vii) [Reserved]

(viii) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

(2) Within 30 days after the date of filing the petition, the Commissioner will place the petition on public file in the office of the Dockets Management Branch and will publish a notice of filing in the FEDERAL REGISTER giving the name of the petitioner and a brief description of the petition including the name of the substance, its proposed use, and any limitations proposed for reasons other than safety. A copy of the notice will be mailed to the petitioner at the time the original is sent to the FEDERAL REGISTER.

(3) The notice of filing in the FEDERAL REGISTER will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch's office.

(4) The Commissioner will evaluate the petition and all available information including all comments received. If the petition and such information provide convincing evidence that the

substance is GRAS as described in § 170.30 he will publish an order in the FEDERAL REGISTER listing the substance as GRAS in Part 182, Part 184, or Part 186 of this chapter, as appropriate.

(5) If, after evaluation of the petition and all available information, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the Act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 170.38.

(6) The notice of filing in the FEDERAL REGISTER will request submission of proof of any applicable prior sanction for use of the ingredient under conditions different from those proposed to be determined to be GRAS. The failure of any person to come forward with proof of such an applicable prior sanction in response to the notice of filing will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice of filing will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the notice of filing.

(Sec. 201, 72 Stat. 1784-1788; 21 U.S.C. 321)

[42 FR 14488, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 50 FR 7492, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985]

§ 170.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 170.35(b)(4) or (c)(5), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS and is a food additive subject to section 409 of the Act.

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 10 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the Act. Any petition shall include all relevant data and information of the type described in § 171.130(b). The Commissioner will place all of the data and information on which he relies on public file in the office of the Dockets Management Branch and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Dockets Management Branch. Copies of all comments shall be made available for examination in the Dockets Management Branch's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the Act, he will publish a notice thereof in the FEDERAL REGISTER. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the FEDERAL REGISTER listing the substance as GRAS in Part 182, Part 134, or Part 186 of this chapter, as appropriate.

(c) A FEDERAL REGISTER notice determining that a substance is a food additive shall provide for the use of the additive in food or food contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(d) If the Commissioner of Food and Drugs is aware of any prior sanction for use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under Part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(Sec. 201, 72 Stat. 1784-1788; 21 U.S.C. 321)

[42 FR 14488, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

Subpart C—Specific Administrative Rulings and Decisions

§ 170.45 Fluorine-containing compounds.

The Commissioner of Food and Drugs has concluded that it is in the interest of the public health to limit the addition of fluorine compounds to foods (a) to that resulting from the fluoridation of public water supplies as stated in § 250.203 of this chapter, (b) to that resulting from the fluoridation of bottled water within the limitation established in § 103.35(d) of this chapter, and (c) to that authorized by regulations (40 CFR Part 180) under section 408 of the Act.

§ 170.50 Glycine (aminoacetic acid) in food for human consumption.

(a) Heretofore, the Food and Drug Administration has expressed the opinion in trade correspondence that glycine is generally recognized as safe for certain technical effects in human food when used in accordance with good manufacturing practice; however:

(1) Reports in scientific literature indicate that adverse effects were found in cases where high levels of glycine were administered in diets of experimental animals.

(2) Current usage information indicates that the daily dietary intake of glycine by humans may be substantially increasing due to changing use patterns in food technology.

Therefore, the Food and Drug Administration no longer regards glycine and its salts as generally recognized as safe for use in human food and all outstanding letters expressing sanction for such use are rescinded.

(b) The Commissioner of Food and Drugs concludes that by May 8, 1971, manufacturers:

(1) Shall reformulate food products for human use to eliminate added glycine and its salts; or

(2) Shall bring such products into compliance with an authorizing food additive regulation. A food additive petition supported by toxicity data is required to show that any proposed level of glycine or its salts added to foods for human consumption will be safe.

(c) The status of glycine as generally recognized as safe for use in animal feed, as prescribed in § 582.5049 of this chapter, remains unchanged because the additive is considered an essential nutrient in certain animal feeds and is safe for such use under conditions of good feeding practice.

(Sec. 201(s), 72 Stat. 1784-88, as amended; 21 U.S.C. 321(s))

§ 170.60 Nitrites and/or nitrates in curing premixes.

(a) Nitrites and/or nitrates are food additives when combined in curing premixes with spices and/or other flavoring or seasoning ingredients that contain or constitute a source of secondary or tertiary amines, including but not limited to essential oils, disodium inosinate, disodium guanylate, hydrolysates of animal or plant origin (such as hydrolyzed vegetable protein), oleoresins of spices, soy products, and spice extractives. Such food additives may be used only after the establishment of an authorizing food additive regulation. A food additive petition submitted pursuant to §§ 171.1 and 171.100 of this chapter, supported by data demonstrating that nitrosamines are not formed in curing premixes containing such food additives, is required to establish safety.

(b) Nitrites and/or nitrates, when packaged separately from flavoring and seasoning in curing premixes, may continue to be used under prior sanctions in the commercial curing of meat and meat products and poultry products and in accordance with the provisions of §§ 172.170 and 172.175 of this chapter that apply to meat curing preparations for the home curing of meat and meat products, including poultry and wild game. To assure safe use of such ingredients the labeling of the premixes shall bear instructions to the user that such separately packaged ingredients are not to be combined until just prior to use. Encapsulating or coating some or all of the ingredients does not constitute separate packaging.

PART 171—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

Sec.
171.1 Petitions.
171.6 Amendment of petition.
171.7 Withdrawal of petition without prejudice.

Subpart B—Administrative Actions on Applications

171.100 Regulation based on petition.
171.102 Effective date of regulation.
171.110 Procedure for objections and hearings.
171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

Authority: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Source: 42 FR 14489, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

——————————
(Date)

Name of petitioner ——————————
Post-office address ——————————
Date ——————————
Name of food additive and proposed use——

——————————

——————————

Petitions Control Branch
Food and Drug Administration
Department of Health and Human Services
Washington, DC 20204.

Dear Sirs:

The undersigned, ——————————submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to ——————

——————————

(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the additive, the expiration date that will be employed.

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food by reason of the use of the food additive. If the additive results or may reasonably be expected to result from the use of packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

(Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.)

(If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.)

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive.

(A petition may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the food additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations that would bias an evaluation of the safety of the food additive.)

F. Proposed tolerances for the food additive, if tolerances are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If submitting petition to modify an existing regulation issued pursuant to section 409(c)(1)(A) of the Act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Yours very truly,
Petitioner ——————————
By ——————————
(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will usually be retained but not filed as a petition under section 409 of the Act. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier. If part of the data have been submitted by the manufacturer of the food additive as a master file, the petitioner may refer to the master file if and to the extent he obtains the manufacturer's written permission to do so. The manufacturer may authorize specific reference to the data without disclosure to the petitioner. Nothing herein shall prevent reference to published data.

(g) A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the Act are lacking or are not set forth so as to be readily understood.

(h)(1) The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(i) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(ii) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) A list of all ingredients contained in a food additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(v) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(2) The following data and information in a food additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(i) Manufacturing methods or processes, including quality control procedures.

(ii) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(iii) Quantitative or semiquantitative formulas.

(3) All correspondence and written summaries of oral discussions relating to a food additive petition are available for public disclosure in accordance with the provisions of Part 20 of this chapter when the food additive regulation is published in the FEDERAL REGISTER.

(4) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and all studies and tests on a food additive for identi-

ty, stability, purity, potency, performance, and usefulness.

(i)(1) Within 15 days after receipt, the Commissioner will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 409(b)(5) of the Act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing.

(2) The Commissioner will publish in the Federal Register within 30 days from the date of filing of such petition, a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. In the case of a food additive which becomes a component of food by migration from packaging material, the notice shall include the name of the migratory substance, and where it is different from that of one of the original components, the name of the parent component, the maximum quantity of the migratory substance that is proposed for use in food, and the physical or other technical effect which the migratory substance or its parent component is intended to have in the packaging material. A copy of the notice will be mailed to the petitioner when the original is forwarded to the Federal Register for publication.

(j) The Commissioner may request a full description of the methods used in, and the facilities and controls used for, the production of the food additive, or a sample of the food additive, articles used as components thereof, or of the food in which the additive is proposed to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the food additive, or articles used as components thereof, or of the food in or on which the additive is proposed to be used, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the food additive present in foods for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the food additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 409(c)(2) of the Act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(l) [Reserved]

(m) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 409(b) of the Act shall include statements regarding each such clinical investigation relied upon in the petition that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in Part 50 of this chapter.

[42 FR 14489, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 46 FR 8952, Jan.

27, 1981; 50 FR 7492, Feb. 22, 1985; 50 16668, Apr. 26, 1985]

§ 171.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

[50 FR 7492, Feb. 22, 1985, as amended at 50 16668, Apr. 26, 1985]

§ 171.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in § 171.100(a) has been forwarded to the Federal Register for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling the time limitation will begin to run anew.

Subpart B—Administrative Actions on Applications

§ 171.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the Federal Register, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the Act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and prior to the forwarding of the order to the Federal Register for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 171.102 Effective date of regulation.

A regulation published in accordance with § 171.100(a) shall become effective upon publication in the Federal Register.

§ 171.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409(c), (d), or (h) of the Act shall be governed by Part 12 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

§ 171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

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172.370 Iron-choline citrate complex.
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Sec.
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Subpart G—Gums, Chewing Gum Bases and Related Substances

172.610 Arabinogalactan.
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172.620 Carrageenan.
172.623 Carrageenan with polysorbate 80.
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172.660 Salts of furcelleran.
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172.710 Adjuvants for pesticide use dilutions.
172.712 Dimethyl dialkyl ammonium chloride.
172.715 Calcium lignosulfonate.
172.720 Calcium lactobionate.
172.725 Gibberellic acid and its potassium salt.
172.730 Potassium bromate.
172.735 Glycerol ester of wood rosin.
172.755 Stearyl monoglyceridyl citrate.
172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).
172.770 Ethylene oxide polymer.
172.775 Methacrylic acid-divinylbenzene copolymer.

Subpart I—Multipurpose Additives

172.802 Acetone peroxides.
172.804 Aspartame.
172.806 Azodicarbonamide.
172.808 Copolymer condensates of ethylene oxide and propylene oxide.
172.810 Dioctyl sodium sulfosuccinate.
172.812 Glycine.
172.814 Hydroxylated lecithin.
172.816 Methyl glucoside-coconut oil ester.
172.818 Oxystearin.
172.820 Polyethylene gylcol (mean molecular weight 200-9,500).
172.822 Sodium lauryl sulfate.
172.824 Sodium mono- and dimethyl naphthalene sulfonates.
172.826 Sodium stearyl fumarate.
172.828 Acetylated monoglycerides.
172.830 Succinylated monoglycerides.
172.832 Monoglyceride citrate.
172.834 Ethoxylated mono- and diglycerides.
172.836 Polysorbate 60.
172.838 Polysorbate 65.
172.840 Polysorbate 80.
172.841 Polydextrose.
172.842 Sorbitan monostearate.
172.844 Calcium stearoyl-2-lactylate.
172.846 Sodium stearoyl-2-lactylate.
172.848 Lactylic esters of fatty acids.
172.850 Lactylated fatty acid esters of glycerol and propylene glycol.
Sec.
172.852 Glyceryl-lacto esters of fatty acids.
172.854 Polyglycerol esters of fatty acids.
172.856 Propylene glycol mono- and diesters of fats and fatty acids.
172.858 Propylene glycol alginate.
172.859 Sucrose fatty acid esters.
172.860 Fatty acids.
172.862 Oleic acid derived from tall oil fatty acids.
172.863 Salts of fatty acids.
172.864 Synthetic fatty alcohols.
172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.
172.868 Ethyl cellulose.
172.870 Hydroxypropyl cellulose.
172.872 Methyl ethyl cellulose.
172.874 Hydroxypropyl methylcellulose.
172.876 Castor oil.
172.878 White mineral oil.
172.880 Petrolatum.
172.882 Synthetic isoparaffinic petroleum hydrocarbons.
172.884 Odorless light petroleum hydrocarbons.
172.886 Petroleum wax.
172.888 Synthetic petroleum wax.
172.890 Rice bran wax.
172.892 Food starch-modified.
172.894 Modified cottonseed products intended for human consumption.
172.896 Dried yeasts.
172.898 Bakers yeast glycan.

AUTHORITY: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

SOURCE: 42 FR 14491, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 172.5 General provisions for direct food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purposes of this part, good manufacturing practice shall be defined to include the following restrictions.

(1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.

(2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.

(b) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to relieve the use of the substance from compliance with any other provision of the act.

(c) The existence of any regulation prescribing safe conditions of use for a nutrient substance does not constitute a finding that the substance is useful or required as a supplement to the diet of humans.

Subpart B—Food Preservatives

§ 172.105 Anoxomer.

Anoxomer as identified in this section may be safely used in accordance with the following conditions:

(a) Anoxomer is 1,4-benzenediol, 2-(1,1-dimethylethyl)-polymer with diethenylbenzene, 4-(1,1-dimethylethyl)phenol, 4- methoxyphenol, 4,4′-(1-methylethylidene)bis(phenol) and 4-methylphenol (CAS Reg. No. 60837-57-2) prepared by condensation polymerization of divinylbenzene (*m*- and *p*-) with *tert*-butylhydroquinone, *tert*-butylphenol, hydroxyanisole, *p*-cresol and 4,4′-isopropylidenediphenol.

(b) The polymeric antioxidant meets the following specifications:

(1) Polymer, not less than 98.0 percent as determined by an ultraviolet method entitled "Ultraviolet Assay, "1982, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Molecular weight: Total monomers, dimers and trimers below 500 not more than 1 percent as determined by a method entitled "Low Molecular Weight Anoxomer Analysis," 1982, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Phenol content: Not less than 3.2 milliequivalent/gram and not more than 3.8 milliequivalent/gram as determined by a method entitled "Total Phenols," 1982, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) Heavy metals as lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 3 parts per million. Mercury (as Hg), not more than 1 part per million.

(c) Anoxomer may be safely used as an antioxidant in food at level of not more than 5,000 parts per million based on fat and oil content of the food.

[48 FR 18798, Apr. 26, 1983]

§ 172.110 BHA.

The food additive BHA (butylated hydroxyanisole) alone or in combination with other antioxidants permitted in food for human consumption in this Subpart B may be safely used in or on specified foods, as follows:

(a) The BHA meets the following specification:

Assay (total BHA), 98.5 percent minimum.
Melting point 48° C minimum.

(b) The BHA is used alone or in combination with BHT, as an antioxidant in foods, as follows:

Food	Limitations (total BHA and BHT) parts per million
Dehydrated potato shreds	50
Active dry yeast	[1] 1,000
Beverages and desserts prepared from dry mixes	[1] 2
Dry breakfast cereals	50
Dry diced glazed fruit	[1] 32
Dry mixes for beverages and desserts	[1] 90
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweetpotato flakes	50

[1] BHA only.

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition

to the other information required by the act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

(3) The label or labeling of dry mixes for beverages and desserts shall bear adequate directions for use to provide that beverages and desserts prepared from the dry mixes contain no more than 2 parts per million BHA.

§ 172.115 BHT.

The food additive BHT (butylated hydroxytoluene), alone or in combination with other antioxidants permitted in this Subpart B may be safely used in or on specified foods, as follows:

(a) The BHT meets the following specification: Assay (total BHT) 99 percent minimum.

(b) The BHT is used alone or in combination with BHA, as an antioxidant in foods, as follows:

Food	Limitations (total BHA and BHT) parts per million
Dehydrated potato shreds	50
Dry breakfast cereals	50
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweetpotato flakes	50

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

§ 172.120 Calcium disodium EDTA.

The food additive calcium disodium EDTA (calcium disodium ethylene-diaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the conditions prescribed, as follows:

(a) The additive contains a minimum of 99 percent by weight of either the dihydrate $C_{10}H_{12}O_8N_2CaNa_2 \cdot 2H_2O$ or the trihydrate $C_{10}H_{12}O_8N_2CaNa_2 \cdot 3H_2O$, or any mixture of the two.

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as the anhydrous compound:

Food	Limitation (parts per million)	Use
Cabbage, pickled	220	Promote color, flavor, and texture retention.
Canned carbonated soft drinks.	33	Promote flavor retention.
Canned white potatoes	110	Promote color retention.
Clams (cooked canned)	340	Promote color retention.
Crabmeat (cooked canned).	275	Retard struvite formation; promote color retention.
Cucumbers pickled	220	Promote color, flavor, and texture retention.
Distilled alcoholic beverages.	25	Promote stability of color, flavor, and/or product clarity.
Dressings, nonstandardized.	75	Preservative.
Dried lima beans (cooked canned).	310	Promote color retention.
Egg product that is hard-cooked and consists, in a cylindrical shape, of egg white with an inner core of egg yolk.	[1] 200	Preservative.
Fermented malt beverages.	25	Antigushing agent.
French dressing	75	Preservative.
Mayonnaise	75	Do.
Mushrooms (cooked canned).	200	Promote color retention.
Oleomargarine	75	Preservative.
Pecan pie filling	100	Promote color retention.
Potato salad	100	Preservative.
Processed dry pinto beans.	800	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.
Shrimp (cooked canned).	250	Retard struvite formation; promote color retention.
Spice extractives in soluble carriers.	60	Promote color and flavor retention.
Spreads, artificially colored and lemon-flavored or orange-flavored.	100	Promote color retention.

[1] By weight of egg yolk portion.

(2) With disodium EDTA (disodium ethylenediaminetetraacetate) in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraph (b) of this section, the additives are used only in compliance with the applicable standards of identity for such foods.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14491, Mar. 15, 1977, as amended at 48 FR 10815, Mar. 15, 1983]

§ 172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109° C-111° C; assay, minimum 98 percent (dry basis).

Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

(b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.

(c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§ 172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

(a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{14}O_8N_2Na_2 \cdot 2H_2O$).

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

Food	Limitation (parts per million)	Use
Aqueous multivitamin preparations.	150	With iron salts as a stabilizer for vitamin B^{12} in liquid multivitamin preparations.
Canned black-eyed peas.	145	Promote color retention.
Canned cooked chickpeas.	165	Do.
Canned kidney beans	165	Preservative.
Canned strawberry pie filling.	500	Promote color retention.
Cooked sausage	36	As a cure accelerator with sodium ascorbate or ascorbic acid.
Dressings, nonstandardized.	75	Preservative.
French dressing	75	Do.
Frozen white potatoes including cut potatoes.	100	Promote color retention.
Gefilte fish balls or patties in packing medium.	[1] 50	Inhibit discoloration.
Mayonnaise	75	Preservative.
Ready-to-eat cereal products containing dried bananas.	[2] 315	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.

[1] Based on total weight of finished product including packing medium.

[2] In dried banana component of cereal product.

(2) With calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate; calcium disodium (ethylenedinitrilo) tetraacetate), in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(3) Alone, as a sequestrant in the nonnutritive sweeteners that are listed in § 180.37 of this chapter and that, in addition, are designed for aqueous solution: *Provided*, That the amount of the additive, calculated as anhydrous calcium disodium EDTA, does not exceed 0.1 percent by weight of the dry nonnutritive sweetener.

(c) To assure the safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraphs (b)(1) and (2) of this section the additives are used only in compliance with the applicable standards of identity for such foods.

§ 172.140 Ethoxyquin.

(a) Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used as an antioxidant for preservation of color in the production of chili powder, paprika, and ground chili at levels not in excess of 100 parts per million.

(b) In order to provide for the safe use of the additive in feed prepared in accordance with §§ 573.380 and 573.400 of this chapter, tolerances are established for residues of ethoxyquin in or on edible products of animals as follows:

5 parts per million in or on the uncooked fat of meat from animals except poultry.
3 parts per million in or on the uncooked liver and fat of poultry.
0.5 part per million in or on the uncooked muscle meat of animals.
0.5 part per million in poultry eggs.
Zero in milk.

§ 172.145 Heptylparaben.

(a) The food additive heptylparaben is the chemical *n*-heptyl *p*-hydroxybenzoate.

(b) It may be safely used to inhibit microbiological spoilage in accordance with the following prescribed conditions:

(1) In fermented malt beverages in amounts not to exceed 12 parts per million.

(2) In noncarbonated soft drinks and fruit-based beverages in amounts not to exceed 20 parts per million, when standards of identity established under section 401 of the Act (21 U.S.C. 341) do not preclude such use.

§ 172.150 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

The food additive 4-hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140° C–141° C.

(b) The additive is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total amount of all antioxidants added to such food shall not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.155 Natamycin (pimaricin).

(a) Natamycin (CAS Reg. No. 7681-93-8), also known as pimaricin, is a polyene macrolide antimycotic substance possessing an empirical formula of $C_{33}H_{47}NO_{13}$ and a molecular weight of 665.7.

(b) The additive shall conform to the following specifications:

Purity: 97 percent ± 2 percent on an anhydrous basis.

Arsenic: Not more than 1 part per million.
Heavy metals (as Pb): Not more than 20 parts per million.

(c) The additive may be applied to the surface of cuts and slices of cheese to inhibit mold spoilage with the following limitations:

(1) The additive may be applied by dipping or by spraying, using an aqueous solution containing 200 to 300 parts per million of the additive.

(2) The additive may be applied to the surface of those cuts and slices of cheese(s) listed in Part 133 of this chapter only if the cheese standards provide for the use of "safe and suitable" mold-inhibiting ingredients.

[47 FR 26823, June 22, 1982, as amended at 50 FR 49536, Dec. 3, 1985]

§ 172.160 Potassium nitrate.

The food additive potassium nitrate may be safely used as a curing agent in the processing of cod roe, in an amount not to exceed 200 parts per million of the finished roe.

§ 172.165 Quaternary ammonium chloride combination.

The food additive, quaternary ammonium chloride combination, may be safely used in food in accordance with the following conditions:

(a) The additive contains the following compounds: *n*-dodecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139-07-1); *n*-dodecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479-28-3); *n*-hexadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122-18-9); *n*-octadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122-19-0); *n*-tetradecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139-08-2); *n*-tetradecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479-29-4).

(b) The additive meets the following specifications: pH (5 percent active solution) 7.0-8.0; total amines, maximum 1 percent as combined free amines and amine hydrochlorides.

(c) The additive is used as an antimicrobial agent, as defined in § 170.3(o)(2) of this chapter, in raw sugar cane juice. It is added prior to clarification when further processing of the sugar cane juice must be delayed.

(d) The additive is applied to the sugar juice in the following quantities, based on the weight of the raw cane:

Component	Parts per million
n-Dodecyl dimethyl benzyl ammonium chloride	0.25-1.0
n-Dodecyl dimethyl ethylbenzyl ammonium chloride	3.4-13.5
n-Hexadecyl dimethyl benzyl ammonium chloride	1.5-6.0
n-Octadecyl dimethyl benzyl ammonium chloride	0.25-1.0
n-Tetradecyl dimethyl benzyl ammonium chloride	3.0-12.0
n-Tetradecyl dimethyl ethylbenzyl ammonium chloride	1.6-6.5

[50 FR 3890, Jan. 29, 1985]

§ 172.170 Sodium nitrate.

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a preservative and color fixative, with or without sodium nitrite, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad, so that the level of sodium nitrate does not exceed 500 parts per million and the level of sodium nitrite does not exceed 200 parts per million in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrate to not more than 500 parts per million in the finished meat product and the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive or of a mixture containing the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and label-

ing of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive or of a mixture containing the additive, shall bear the statement "Keep out of the reach of children".

§ 172.175 Sodium nitrite.

The food additive sodium nitrite may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a color fixative in smoked cured tunafish products so that the level of sodium nitrite does not exceed 10 parts per million (0.001 percent) in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrate, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad so that the level of sodium nitrite does not exceed 200 parts per million and the level of sodium nitrate does not exceed 500 parts per million in the finished product.

(3) As a preservative and color fixative, with sodium nitrate, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrite to not more than 200 parts per million in the finished meat product, and the amount of sodium nitrate to not more than 500 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive or of a mixture containing the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive, or of a mixture containing the additive, shall bear the statement "Keep out of the reach of children".

§ 172.177 Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

(a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.

(b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.

(c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160°F for a minimum of 30 minutes.

(d) The finished product shall be cooled to a temperature of 50° F or below within 3 hours after smoking and further cooled to a temperature of 38° F or below within 12 hours after smoking. A temperature of 38° F or below shall be maintained during all subsequent storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38° F or below) until consumed.

(e) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions to assure use in compliance with the provisions of this section.

§ 172.180 Stannous chloride.

The food additive stannous chloride may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material, in an amount not to exceed 20 parts per million calculated as tin (Sn).

§ 172.185 TBHQ.

The food additive TBHQ, which is the chemical 2-(1,1-dimethylethyl)-1,4-benzenediol (Chemical Abstracts Service Registry Number 1948-33-0), also known as tertiary butylhydroquinone, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 126.5°C-128.5°C.

(b) It is used as an antioxidant alone or in combination with BHA and/or BHT.

(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.190 THBP.

The food additive THBP (2,4,5-trihydroxybutyrophenone) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 149°C-153°C.

(b) It is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

Subpart C—Coatings, Films and Related Substances

§ 172.210 Coatings on fresh citrus fruit.

Coatings may be applied to fresh citrus fruit for protection of the fruit in accordance with the following conditions:

(a) The coating is applied in the minimum amount required to accomplish the intended effect.

(b) The coating may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose or previously sanctioned for the purpose.

(2) One or more of the following:

Component	Limitations
Fatty acids	Complying with § 172.860.
Oleic acid derived from tall oil fatty acids	Complying with § 172.862.
Partially hydrogenated rosin	Catalytically hydrogenated to a maximum refractive index of 1.5012 at 100° C. Color of WG or paler.
Pentaerythritol ester of maleic anhydride-modified wood rosin.	Acid number of 134–145; drop-softening point of 127° C–173° C; saponification number of less than 280; and a color of M or paler.
Do	Acid number of 176–186; drop-softening point of 110° C–118° C; saponification number of less than 280; and a color of M or paler.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyhydric alcohol diesters of oxidatively refined (Gersthofen process) montan wax acids.	Complying with § 178.3770 of this chapter and having a dropping point of 77 to 83° C (170.6 to 181.4° F), as determined by ASTM Method D566-76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference (copies are available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using as a solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.
Sodium lauryl sulfate	Complying with § 172.822. As a film former.

Component	Limitations
Wood rosin	Color of K or paler.

(3) In lieu of the components listed in paragraph (b)(2) and (4) of this section, the following copolymer and one or more of the listed adjuvants.

Component	Limitations
Vinyl chloride-vinylidene chloride copolymer	As an aqueous dispersion containing a minimum of 75 percent water when applied.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyvinylpyrrolidone	As an adjuvant.
Potassium persulfate	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Propylene glycol alginate	Do.
Sodium decylbenzenesulfonate	Do.

(4) In lieu of the components listed in paragraph (b)(2) and (3) of this section, the following rosin derivative and either or both of the listed adjuvants:

Component	Limitations
Calcium salt or partially dimerized rosin	Having a maximum drop-softening point of 197° C and a color of H or paler. It is prepared by reaction with not more than 7 parts hydrated lime per 100 parts of partially dimerized rosin. The partially dimerized rosin is rosin that has been dimerized by sulfuric acid catalyst to a drop-softening point of 95° C to 105° C and a color of WG or paler.
Petroleum naphtha	As adjuvant. Complying with § 172.250.
Sperm oil	As adjuvant.

[42 FR 14491, Mar. 15, 1977; 49 FR 5747, Feb. 15, 1984, as amended at 51 FR 2693, Jan. 21, 1986]

§ 172.215 Coumarone-indene resin.

The food additive coumarone-indene resin may be safely used on grapefruit, lemons, limes, oranges, tangelos, and tangerines in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the polymerization of a crude, heavy coal-tar solvent naphtha meeting the following specifications:

(1) It is a mixture of indene, indan (hydrindene), substituted benzenes, and related compounds.

(2) It contains no more than 0.25 percent tar bases.

(3) 95 percent distills in the range 167° C-184° C.

(b) The food additive meets the following specifications:

(1) Softening point, ring and ball: 126° C minimum as determined by ASTM method E28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Refractive index (n^{25}/D) 1.63-1.64.

(c) It is used or intended for use as a protective coating for grapefruit, lemons, limes, oranges, tangelos, and tangerines whereby the maximum amount of the resin remaining on the fruit does not exceed 200 parts per million on a fresh-weight basis.

(d) To assure safe use of the additive:

(1) The label of the market package or any intermediate premix of the additive shall bear, in addition to the other information required by the act:

(i) The name of the additive, coumarone-indene resin.

(ii) A statement of the concentration of the additive therein.

(2) The label or accompanying labeling shall bear adequate directions

that, if followed, will result in a finished food not in conflict with the requirements of this section.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10103, Mar. 19, 1984]

§ 172.225 Methyl esters of fatty acids produced from edible fats and oils.

Methyl esters of fatty acids produced from edible fats and oils may be safely used in food, subject to the following prescribed conditions:

(a) The additive consists of a mixture of methyl esters of fatty acids produced from edible fats and oils and meets the following specifications:

(1) Not less than 90 percent methyl esters of fatty acids.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at a level not to exceed 3 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 200 parts per million.

§ 172.230 Microcapsules for flavoring substances.

Microcapsules may be safely used for encapsulating discrete particles of flavoring substances that are generally recognized as safe for their intended use or are regulated under this part, in accordance with the following conditions:

(a) The microcapsules may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose.

(2) One or more of the following components:

Component and Limitations

Succinylated gelatin—Not to exceed 15 percent by combined weight of the microcapsule and flavoring oil. Succinic acid content of the gelatin is 4.5 to 5.5 percent.

Arabinogalactan—Complying with § 172.610; as adjuvant.

Silicon dioxide—Complying with § 172.480; as adjuvant.

(3) In lieu of the components listed in paragraph (a)(2) of this section, the following components:

Component and Limitations

Glutaraldehyde—As cross-linking agent for insolubilizing a coacervate of gum arabic and gelatin.

n-Octyl alcohol—As a defoamer.

(4) In lieu of the components listed in paragraphs (a)(2) and (3) of this section, the following component:

Component and Limitations

Petroleum wax—Complying with § 172.886. Not to exceed 50 percent by combined weight of the microcapsule and spice-flavoring substance.

(b) The microcapsules produced from the components listed in paragraphs (a) (1), (2), and (3) of this section may be used for encapsulating authorized flavoring oils for use, in accordance with good manufacturing practice, in foods for which standards of identity established under section 401 of the Act do not preclude such use, except that microcapsules formulated from components listed in paragraph (a)(2) of this section may be used only for encapsulating lemon oil, distilled lime oil, orange oil, peppermint oil, and spearmint oil for use in dry mixes for puddings and gelatin desserts.

(c) The microcapsules produced from the components listed in paragraphs (a) (1) and (4) of this section may be used only for encapsulating authorized spice-flavoring substances for use, in accordance with good manufacturing practice, in frozen pizzas which are to be further processed by heat. Such pizzas shall bear labels or labeling including adequate directions for use to ensure heating to temperatures which will melt the wax to release the spice-flavoring substances.

[45 FR 48123, July 18, 1980]

§ 172.235 Morpholine.

Morpholine may be safely used as a component of food, subject to the following restrictions.

(a) It is used as the salt(s) of one or more of the fatty acids meeting the requirements of § 172.860, as a component of protective coatings applied to fresh fruits and vegetables.

(b) It is used at a level not in excess of that reasonably required to produce its intended effect.

§ 172.250 Petroleum naphtha.

Petroleum naphtha may be safely used in food in accordance with the following conditions:

(a) The additive is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum,

(b) The additive is refined to meet the following specifications when subjected to the procedures described in this paragraph.

(1) Boiling-point range: 175° F-300° F.

(2) Nonvolatile residue: 0.002 gram per 100 milliliters maximum.

(3) Ultraviolet absorbance limits, as follows:

Wavelength (milli-microns)	Maximum absorbance per centimeter optical pathlength
280–289	0.15
290–299	.13
300–359	.08
360–400	.02

ANALYTICAL SPECIFICATION FOR PETROLEUM NAPHTHA

GENERAL INSTRUCTIONS

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of petroleum naphtha samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, and 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Erlenmeyer flask. 125-milliliter with 24/40 standard taper neck.

Evaporation flask. 250-milliliter capacity all-glass flask equipped with 24/40 standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of the container liquid to be evaporated.

Condenser. 24/40 joints, fitted with drying tube, length optional.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250-400 $m\mu$ with spectral slit width of 2 $m\mu$ or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.
Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.
Wavelength repeatability, ±0.2 millimicron.
Wavelength accuracy, ±1.0 millimicron.

Ultraviolet lamp. Long wavelength (3400-3800A°).

REAGENTS

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane, insert the head assembly, allow nitrogen gas to flow into the inlet tube and connect the outlet tube to a solvent trap and vacuum line in such a way as to prevent any back flow of condensate into the flask. The contents of the flask are evaporated on a steam bath until 1 milliliter of residue remains. Dissolve the 1 milliliter of hexadecane residue in isooctane and make up to 25 milliliters. Determine the absorbance in a 5-centimeter path length cell compared to isooctane as reference. The absorbance should not exceed 0.01 per centimeter path length between 280-400 mμ. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davidson Chemical Co., Baltimore, Md., or equivalent) or by distillation.

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[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. The procedure is incorporated by reference. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal register, 1100 L St. NW., Washington, DC 20408.

Methyl alcohol, A.C.S. reagent grade. Use 10 milliliters and proceed as with isooctane. The absorbance per centimeter of path length should be 0.00 between 280-400 mμ. Methyl alcohol may be purified by simple distillation or by refluxing in the presence of potassium hydroxide (10 grams/2 liters) and zinc dust (25 grams/2 liters) for 3 hours followed by distillation.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of n-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference between 280-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Sodium borohydride. 98 percent.

Water. All distilled water must be extracted with isooctane before use. A series of three successive extracts of 1.5 liters of distilled water with 100-milliliter portions of isooctane is satisfactory.

PROCEDURE

Determination of ultraviolet absorbance. Add a 25-milliliter aliquot of the hydrocarbon solvent together with 1 milliliter of hexadecane to the 125-milliliter Erlenmeyer flask. While flushing with nitrogen, evaporate to 1 milliliter on a steam bath. Nitrogen is admitted through a 8±1-milliliter outer-diameter tube, drawn out into a 2±1-centimeter long and 1±0.5-millimeter inner-diameter capillary tip. This is positioned so that the capillary tip extends 4 centimeters into the flask. The nitrogen flow rate is such that the surface of the liquid is barely disturbed. After the volume is reduced to that of the 1 milliliter of hexadecane, the flask is left on the steam bath for 10 more minutes before removing. Add 10 milliliters of purified isooctane to the flask and reevaporate the solution to a 1-milliliter volume in the same manner as described above, except do not heat for an added 10 minutes. Repeat this operation twice more. Let the flask cool.

Add 10 milliliters of methyl alcohol and about 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere; a measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the sodium borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this time, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until sodium borohydride begins to drop out of solution. Remove the flask and let it cool.

Add 6 milliliters of isooctane to the flask and swirl to wash the crystalline slurry. Carefully transfer the isooctane extract to a 250-milliliter separatory funnel. Dissolve the crystals in the flask with about 25 milliliters of distilled water and pour this also into the separatory funnel. Adjust the water volume in the separatory funnel to about 100 milliliters and shake for 1 minute. After separation of the layers, draw off the aqueous layer into a second 250-milliliter separatory funnel. Transfer the hydrocarbon layer in the first funnel to a 25-milliliter volumetric flask.

Carefully wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the second separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer into the first separatory funnel. Transfer the isooctane in the second funnel to the volumetric flask. Again wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the first separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer and discard. Transfer the isooctane layer to the volumetric flask and adjust the volume to 25 milliliters of isooctane. Mix the contents well, then transfer to the first separatory funnel and wash twice with 50-milliliter portions of distilled water. Discard the aqueous layers after each wash.

Determine the ultraviolet absorbance of the isooctane extract in 5-centimeter path length cells compared to isooctane as reference between 280-400 mμ. Determine a reagent blank concurrently with the sample, using 25 milliliters of purified isooctane instead of a solvent sample and measuring the ultraviolet absorbance of the blank between 280-400mμ.

The reagent blank absorbance should not exceed 0.04 per centimeter path length between 280-289 mμ; 0.020 between 290-359 mμ; and 0.010 between 360-400 mμ.

Determination of boiling-point range. Use ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Determination of nonvolatile residue. For hydrocarbons boiling below 121° C, determine the nonvolatile residue by ASTM method D1353-78, "Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;" for those boiling above 121° C, use ASTM method D381-80, "Standard Test Method for Existent Gum in Fuels by Jet Evaporation," which methods are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) Petroleum naphtha containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. Petroleum naphtha may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended effect or to exceed any prescribed limitations.

(d) Petroleum naphtha is used or intended for use as a solvent in protective coatings on fresh citrus fruit in compliance with § 172.210.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11835, Mar. 19, 1982; 49 FR 10104, Mar. 19, 1984]

§ 172.255 Polyacrylamide.

Polyacrylamide containing not more than 0.2 percent of acrylamide monomer may be safely used as a film former in the imprinting of soft-shell gelatin capsules when the amount used is not in excess of the minimum required to produce the intended effect.

§ 172.260 Oxidized polyethylene.

Oxidized polyethylene may be safely used as a component of food, subject to the following restrictions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene. The polyethylene used in the oxidation process conforms to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed in item 2.3 of the table in § 177.1520(c) of this chapter. The oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry; contains a maximum of 5 percent by weight of total oxygen; and has an acid value of 9 to 19.

(b) The additive is used or intended for use as a protective coating or component of protective coatings for fresh avocados, bananas, beets, coconuts, eggplant, garlic, grapefruit, lemons, limes, mango, muskmelons, onions, oranges, papaya, peas (in pods), pineapple, plantain, pumpkin, rutabaga, squash (acorn), sweetpotatoes, tangerines, turnips, watermelon, Brazil nuts, chestnuts, filberts, hazelnuts, pecans, and walnuts (all nuts in shells).

(c) The additive is used in accordance with good manufacturing practice and in an amount not to exceed that required to produce the intended effect.

§ 172.275 Synthetic paraffin and succinic derivatives.

Synthetic paraffin and succinic derivatives identified in this section may be safely used as a component of food, subject to the following restrictions:

(a) The additive is prepared with 50 percent Fischer-Tropsch process synthetic paraffin, meeting the definition and specifications of § 172.615, and 50 percent of such synthetic paraffin to which is bonded succinic anhydride and succinic acid derivatives of isopropyl alcohol, polyethylene glycol, and polypropylene glycol. It consists of a mixture of the Fischer-Tropsch process paraffin (alkane), alkyl succinic anhydride, alkyl succinic anhydride isopropyl half ester, dialkyl succinic anhydride polyethylene glycol half ester, and dialkyl succinic anhydride polypropylene glycol half ester, where the alkane (alkyl) has a chain length of 30-70 carbon atoms and the polyethylene and polypropylene glycols have molecular weights of 600 and 260, respectively.

(b) The additive meets the following specifications: Molecular weight, 880-930; melting point, 215°-217° F; acid number, 43-47; and saponification number, 75-78.

(c) It is used or intended for use as a protective coating or component of protective coatings for fresh grapefruit, lemons, limes, muskmelons, oranges, sweetpotatoes, and tangerines.

(d) It is used in an amount not to exceed that required to produce the intended effect.

§ 172.280 Terpene resin.

The food additive terpene resin may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the betapinene polymer obtained by polymerizing terpene hydrocarbons derived from wood. It has a softening point of 112° C-118° C, as determined by ASTM method E28-67 (Reapproved 1982), "Standard Test Method for Softening Point By Ring-and-Ball Apparatus," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) It is used or intended for use as follows:

(1) As a moisture barrier on soft gelatin capsules in an amount not to exceed 0.07 percent of the weight of the capsule.

(2) As a moisture barrier on powders of ascorbic acid or its salts in an amount not to exceed 7 percent of the weight of the powder.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984]

Subpart D—Special Dietary and Nutritional Additives

§ 172.310 Aluminum nicotinate.

Aluminum nicotinate may be safely used as a source of niacin in foods for special dietary use. A statement of the concentration of the additive, expressed as niacin, shall appear on the label of the food additive container or on that of any intermediate premix prepared therefrom.

§ 172.315 Nicotinamide-ascorbic acid complex.

Nicotinamide-ascorbic acid complex may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the controlled reaction between ascorbic acid and nicotinamide, melting in the range 141°C to 145°C.

(b) It is used as a source of ascorbic acid and nicotinamide in multivitamin preparations.

§ 172.320 Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated or anhydrous form or as the hydrochloride, sodium or potassium salts:

L-Alanine
L-Arginine
L-Asparagine
L-Aspartic acid
L-Cysteine
L-Cystine
L-Glutamic acid
L-Glutamine
Aminoacetic acid (glycine)
L-Histidine
L-Isoleucine
L-Leucine
L-Lysine
DL-Methionine (not for infant foods)
L-Methionine
L-Phenylalanine
L-Proline
L-Serine
L-Threonine
L-Tryptophan
L-Tyrosine
L-Valine

(b) The food additive meets the following specifications:

(1) As found in "Food Chemicals Codex," National Academy of Sciences/National Research Council (NAS/NRC), 3d Ed. (1981), which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) for the following:

L-Alanine

L-Arginine
L-Arginine Monohydrochloride
L-Cysteine Monohydrochloride
L-Cystine
Aminoacetic acid (glycine)
L-Leucine
L-Methionine
L-Methionine
L-Tryptophan
L-Phenylalanine
L-Proline
L-Serine
L-Threonine
Glutamic Acid Hydrochloride
L-Isoleucine
L-Lysine Monohydrochloride
Monopotassium *L*-glutamate
L-Tyrosine
L-Valine

(2) As found in "Specifications and Criteria for Biochemical Compounds," NAS/NRC Publication, 3rd Ed. (1972), which is incorporated by reference (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) for the following:

L-Asparagine
L-Aspartic acid
L-Glutamine
L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the "reference" adult male recommended by the National Academy of Sciences in "Recommended Dietary Allowances," NAS Publication No. 1694, 7th Ed. (1968), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily-intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine	6.1
L-Arginine	6.6
L-Aspartic acid (including L-asparagine)	7.0
L-Cystine (including L-cysteine)	2.3
L-Glutamic acid (including L-glutamine)	12.4
Aminoacetic acid (glycine)	3.5
L-Histidine	2.4
L-Isoleucine	6.6
L-Leucine	8.8
L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212-43.216, "Official Methods of Analysis of the Association of Official

Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of Part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 11836, Mar. 19, 1982; 49 FR 10104, Mar. 19, 1984]

§ 172.325 Bakers yeast protein.

Bakers yeast protein may be safely used in food in accordance with the following conditions:

(a) Bakers yeast protein is the insoluble proteinaceous material remaining after the mechanical rupture of yeast cells of *Saccharomyces cerevisiae* and removal of whole cell walls by centrifugation and separation of soluble cellular materials.

(b) The additive meets the following specifications on a dry weight basis:

(1) Zinc salts less than 500 parts per million (ppm) as zinc.

(2) Nucleic acid less than 2 percent.

(3) Less than 0.3 ppm arsenic, 0.1 ppm cadmium, 0.4 ppm lead, 0.05 ppm mercury, and 0.3 ppm selenium.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

§ 172.330 Calcium pantothenate, calcium chloride double salt.

The food additive calcium chloride double salt of calcium pantothenate may be safely used in foods for special dietary uses in accordance with good manufacturing practice and under the following prescribed conditions:

(a) The food additive is of the *d* (dextrorotatory) or the *dl* (racemic) form.

(b) To assure safe use of the additive, the label and labeling of the food additive container, or that of any intermediate premixes prepared therefrom, shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive "calcium chloride double salt of *d*-calcium pantothenate" or "calcium chloride double salt of *dl*-calcium pantothenate", whichever is appropriate.

(2) A statement of the appropriate concentration of the additive, expressed as pantothenic acid.

§ 172.335 D-Pantothenamide.

The food additive D-pantothenamide as a source of pantothenic acid activity, may be safely used in foods for special dietary use in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary conditions. These conditions shall be in accordance with recognized good manufacturing practice for fish to be used as human food.

(4) The additive shall be prepared by extraction with hexane and food-grade ethanol to remove fat and moisture. Solvent residues shall be reduced by drying.

(b) The food additive meets the following specifications: (Where methods of determination are specified, they are Association of Official Analytical Chemists Methods, 13th ed., 1980, which are incorporated by reference).[1]

(1) Protein content, as N X 6.25, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per million of hexane and 3.5 percent ethanol by weight.

[46 FR 38072, July 24, 1981, as amended at 47 FR 53344, Nov. 26, 1982]

§ 172.345 Folic acid (folacin).

Folic acid (folacin) may be safely added to a food for its vitamin property, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 milligram for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 0.1 milligram for infants, 0.3 milligram for children under 4 years of age, 0.4 milligram for adults and children 4 or more years of age, and 0.8 milligram for pregnant or lactating women.

§ 172.350 Fumaric acid and salts of fumaric acid.

Fumaric acid and its calcium, ferrous, magnesium, potassium, and sodium salts may be safely used in food in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) Fumaric acid contains a minimum of 99.5 percent by weight of fu-

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[1] Copies are available from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

maric acid, calculated on the anhydrous basis.

(2) The calcium, magnesium, potassium, and sodium salts contain a minimum of 99 percent by weight of the respective salt, calculated on the anhydrous basis. Ferrous fumarate contains a minimum of 31.3 percent total iron and not more than 2 percent ferric iron.

(b) With the exception of ferrous fumarate, fumaric acid and the named salts are used singly or in combination in food at a level not in excess of the amount reasonably required to accomplish the intended effect.

(c) Ferrous fumarate is used as a source of iron in foods for special dietary use, when the use is consistent with good nutrition practice.

§ 172.365 Kelp.

Kelp may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women. The food additive kelp is the dehydrated, ground product prepared from *Macrocystis pyrifera, Laminaria digitata, Laminaria saccharina*, and *Laminaria cloustoni*.

§ 172.370 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in foods for special dietary use.

§ 172.372 N-Acetyl-L-methionine.

The food additive *N*-acetyl-L-methionine may be safely added to food (except infant foods and foods containing added nitrites/nitrates) as a source of L-methionine for use as a nutrient in accordance with the following conditions:

(a) *N*-Acetyl-L-methionine (Chemical Abstracts Service Registry No. 65-82-7) is the derivative of the amino acid methionine formed by addition of an acetyl group to the *alpha*-amino group of methionine. It may be in the free, hydrated or anhydrous form, or as the sodium or potassium salts.

(b) The additive meets the following specifications:

(1) Purity assay, on a dry basis: Minimum 99 percent.

(2) Residue on ignition: Maximum 0.1 percent.

(3) Specific optical rotation $[\text{alpha}]^{20}_{D}$: Between −19° and −23°.

(4) The additive may contain residues of not more than 500 ppm ethyl acetate; 50 ppm ethyl alcohol; 10 ppm methyl alcohol; and 10 ppm acetone, when used as processing solvents.

(c) The additive is used or intended for use as a source of L-methionine to improve significantly the biological quality of the total protein in a food containing naturally occurring primarily intact vegetable protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact vegetable protein.

(2) The additive results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) The use of the additive results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the additive to achieve the desired effect must be used, and the increase in PER over the primarily intact naturally occurring vegetable protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purpose shall not exceed the level that will provide a total of 3.1 percent L- and DL-methio-

nine (expressed as the free amino acid) by weight of the total protein of the finished food, including the amount naturally present in free and combined (as protein) form.

(5) The additive shall not be added to infant foods or to foods containing added nitrites/nitrates.

(d) Compliance with the limitations concerning PER under paragraph (c) of the section shall be determined by the method described in sections 43.212-43.216, "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington. DC 20408. Each manufacturer or person employing the additive under the provisions of this section shall keep and maintain throughout the period of use of the additive and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation. Those records shall be made available upon request at all reasonable hours by any officer or employee acting on behalf of the Secretary of Health and Human Services. Those officers or employees shall be permitted to conduct inventories of raw and finished materials on hand as are deemed necessary to verify the records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive contained therein.

(2) The amounts of additive and each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) When the food additive is added as a nutrient to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and these foods comply with the requirements of Part 105 of this chapter, the food additive is exempt from the limitations in paragraphs (c)(1) through (4) and (d) of this section and may be used in those foods at levels not to exceed good manufacturing practices.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[43 FR 27784, June 27, 1978, as amended at 46 FR 59968, Dec. 8, 1981; 49 FR 10104, Mar. 19, 1984]

§ 172.375 Potassium iodide.

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:

(1) The name of the additive.

(2) A statement of the concentration of the additive in any mixture.

§ 172.385 Whole fish protein concentrate.

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hakelike fish, herring of the genera *Clupea*, menhaden, and anchovy of the species *Engraulis mordax*, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications:

(1) Protein content (N x 6.25) shall not be less than 75 percent by weight of the final product, as determined by the method described in section 2.057 in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980). Protein quality shall not be less than 100, as determined by the method described in sections 43.212-43.216 of the AOAC. The 13th Ed. is incorporated by reference, and copies may be obtained from the Association of Official Analytical Chemists, P.O Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Moisture content shall not exceed 10 percent by weight of the final product, as determined by the method described in section 24.003 of the AOAC. See paragraph (c)(1) of this section for availability of the material incorporated by reference.

(3) Fat content shall not exceed 0.5 percent by weight of the final product, as determined by the method described in section 24.005 of the AOAC. See paragraph (c)(1) of the this section for availability of the material incorporated by reference.

(4) The additive may contain residues of isopropyl alcohol and ethylene dichloride not in excess of 250 parts per million and 5 parts per million, respectively, when used as solvents in the extraction process.

(5) Microwave radiation meeting the requirements of § 179.30 of this chapter may be used to reduce residues of the solvents used in the extraction process.

(6) The additive shall contain not in excess of 100 parts per million fluorides (expressed as F).

(7) The additive shall be free of *Escherichia coli* and pathogenic organisms, including *Salmonella*, and shall have a total bacterial plate count of not more than 10,000 per gram.

(8) The additive shall have no more than a faint characteristic fish odor and taste.

(d) When the additive is used or intended for use in the household as a protein supplement in food for regular consumption by children up to 8 years of age, the amount of the additive from this source shall not exceed 20 grams per day (about one heaping tablespoon).

(e) When the additive is used as a protein supplement in manufactured food, the total fluoride content (expressed as F) of the finished food shall not exceed 8 ppm based on the dry weight of the food product.

(f) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of consumer-sized or bulk containers of the additive shall bear the name "whole fish protein concentrate".

(2) The label or labeling of containers of the additive shall bear adequate directions for use to comply with the limitations prescribed by paragraphs (d) and (e) of this section.

(3) Labels of manufactured foods containing the additive shall bear, in the ingredient statement, the name of the additive, "whole fish protein concentrate" in the proper order of decreasing predominance in the finished food.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74

Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984]

§ 172.395 Xylitol.

Xylitol may be safely used in foods for special dietary uses, provided the amount used is not greater than that required to produce its intended effect.

§ 172.399 Zinc methionine sulfate.

Zinc methionine sulfate, CAS Reg. No. 56329-42-1, may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the reaction between equimolar amounts of zinc sulfate and DL-methionine in purified water.

(b) The additive meets the following specifications:

Zinc content—19 to 22 percent.

$C_5H_{11}NO_2S$ "DL-methionine"—46 to 50 percent.

Cadmium—not more than 0.05 part per million.

(c) The additive is used in tablet form as a source of dietary zinc.

[46 FR 58297, Dec. 1, 1981]

Subpart E—Anticaking Agents

§ 172.410 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used in food in accordance with the following prescribed conditions:

(a) It is used as an anticaking agent in food in an amount not in excess of that reasonably required to produce its intended effect.

(b) It will not exceed 2 percent by weight of the food, except that it may be present up to 5 percent by weight of baking powder.

§ 172.430 Iron ammonium citrate.

Iron ammonium citrate may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used, or intended for use as an anticaking agent in salt for human consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.480 Silicon dioxide.

The food additive silicon dioxide may be safely used in food in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used as an anticaking agent, subject to the following conditions:

(1) It is used in only those foods in which the additive has been demonstrated to have an anticaking effect.

(2) It is used in an amount not in excess of that reasonably required to produce its intended effect.

(3) [Reserved]

(4) It is used in an amount not to exceed 2 percent by weight of the food.

(c) It is used or intended for use as a stabilizer in the production of beer, and is removed from the beer by filtration prior to final processing.

(d) It is used or intended for use as an adsorbent for *dl-a*-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use, in an amount not greater than that required to accomplish the intended physical or technical effect.

§ 172.490 Yellow prussiate of soda.

(a) The food additive yellow prussiate of soda (sodium ferrocyanide decahydrate; $Na_4FE(CN_6.10H_2O)$ contains a minimum of 99 percent by weight of sodium ferrocyanide decahydrate.

(b) The additive is used or intended for use as an anticaking agent in salt and as an adjuvant in the production of dendritic crystals of salt in an amount needed to produce its intended effect but not in excess of 13 parts per million calculated as anhydrous sodium ferrocyanide.

Subpart F—Flavoring Agents and Related Substances

§ 172.510 Natural flavoring substances and natural substances used in conjunction with flavors.

Natural flavoring substances and natural adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended physical or technical effect and in accordance with all the principles of good manufacturing practice.

(b) In the appropriate forms (plant parts, fluid and solid extracts, concretes, absolutes, oils, gums, balsams, resins, oleoresins, waxes, and distillates) they consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, previously sanctioned for such use, or regulated in any section of this part.

Common name	Scientific name	Limitations
Aloe	*Aloe perryi* Baker, *A. barbadensis* Mill., *A. ferox* Mill., and hybrids of this sp. with *A. africana* Mill. and *A. spicata* Baker.	
Althea root and flowers	*Althea officinalis* L.	
Amyris (West Indian sandalwood)	*Amyris balsamifera* L.	
Angola weed	*Roccella fuciformis* Ach	In alcoholic beverages only.
Arnica flowers	*Arnica montana* L., *A. fulgens* Pursh, *A. sororia* Greene, or *A. cordifolia* Hooker.	Do.
Artemisia (wormwood)	*Artemisia* spp	Finished food thujone free.[1]
Artichoke leaves	*Cynara scolymus* L	In alcoholic beverages only.
Benzoin resin	*Styrax benzoin* Dryander, *S. paralleloneurus* Perkins, *S. tonkinensis* (Pierre) Craib ex Hartwich, or other spp. of the Section *Anthostyrax* of the genus *Styrax*.	
Blackberry bark	*Rubus*, Section *Eubatus*.	
Boldus (boldo) leaves	*Peumus boldus* Mol	Do.
Boronia flowers	*Boronia megastigma* Nees.	
Bryonia root	*Bryonia alba* L., or *B. diocia* Jacq	Do.
Buchu leaves	*Barosma betulina* Bartl. et Wendl., *B. crenulata* (L.) Hook. or *B. serratifolia* Willd..	
Buckbean leaves	*Menyanthes trifoliata* L	Do.
Cajeput	*Melaleuca leucadendron* L. and other *Melaleuca* spp.	
Calumba root	*Jateorhiza palmata* (Lam.) Miers	Do.
Camphor tree	*Cinnamomum camphora* (L.) Nees et Eberm	Safrole free.
Cascara sagrada	*Rhamnus purshiana* DC	
Cassie flowers	*Acacia farnesiana* (L.) Willd.	
Castor oil	*Ricinus communis* L	
Catechu, black	*Acacia catechu* Willd.	
Cedar, white (aborvitae), leaves and twigs.	*Thuja occidentalis* L	Finished food thujone free.[1]
Centuary	*Centaurium umbellatum* Gilib	In alcoholic beverages only.
Cherry pits	*Prunus avium* L. or *P. cerasus* L	Not to exceed 25 p.p.m. prussic acid.
Cherry-laurel leaves	*Prunus laurocerasus* L	Do.
Chestnut leaves	*Castanea dentata* (Marsh.) Borkh	
Chirata	*Swertia chirata* Buch.-Ham	In alcoholic beverages only.
Cinchona, red, bark	*Cinchona succirubra* Pav. or its hybrids	In beverages only; not more than 83 p.p.m. total cinchona alkaloids in finished beverage.
Cinchona, yellow, bark	*Cinchona ledgeriana* Moens, *C. calisaya* Wedd., or hybrids of these with other spp. of *Cinchona*..	Do.
Copaiba	South American spp. of *Copaifera* L.	
Cork, oak	*Quercus suber* L., or *Q. occidentalis* F. Gay	In alcoholic beverages only.
Costmary	*Chrysanthemum balsamita* L	Do.
Costus root	*Saussurea lappa* Clarke.	
Cubeb	*Piper cubeba* L. f.	
Currant, black, buds and leaves	*Ribes nigrum* L	
Damiana leaves	*Turnera diffusa* Willd.	
Davana	*Artemisia pallens* Wall.	

Common name	Scientific name	Limitations
Dill, Indian	*Anethum sowa* Roxb. (*Peucedanum graveolens* Benth et Hook., *Anethum graveolens* L.).	
Dittany (fraxinella) roots	*Dictamnus albus* L.	Do.
Dittany of Crete	*Origanum dictamnus* L.	
Dragon's blood (dracorubin)	*Daemonorops* spp.	
Elder tree leaves	*Sambucus nigra* L.	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor.
Elecampane rhizome and roots	*Inula helenium* L.	In alcoholic beverages only.
Elemi	*Canarium commune* L. or *C. luzonicum* Miq.	
Erigeron	*Erigeron canadensis* L.	
Eucalyptus globulus leaves	*Eucalyptus globulus* Labill.	
Fir ("pine") needles and twigs	*Abies sibirica* Ledeb., *A. alba* Mill., *A. sachalinesis* Masters or *A. mayriana* Miyabe et Kudo.	
Fir, balsam, needles and twigs	*Abies balsamea* (L.) Mill.	
Galanga, greater	*Alpinia galanga* Willd.	Do.
Galbanum	*Ferula galbaniflua* Boiss. et Buhse and other *Ferula* spp.	
Gambir (catechu, pale)	*Uncaria gambir* Roxb.	
Genet flowers	*Spartium junceum* L.	
Gentian rhizome and roots	*Gentiana lutea* L.	
Gentian, stemless	*Gentiana acaulis* L.	Do.
Germander, chamaedrys	*Teucrium chamaedrys* L.	Do.
Germander, golden	*Teucrium polium* L.	Do.
Guaiac	*Guaiacum officinale* L., *G. santum* L., *Bulnesia sarmienti* Lor.	
Guarana	*Paullinia cupana* HBK.	
Haw, black, bark	*Viburnum prunifolium* L.	
Hemlock needles and twigs	*Tsuga canadensis* (L.) Carr. or *T. heterophylla* (Raf.) Sarg.	
Hyacinth flowers	*Hyacinthus orientalis* L.	
Iceland moss	*Cetraria islandica* Ach.	Do.
Imperatoria	*Peucedanum ostruthium* (L.). Koch (*Imperatoria ostruthium* L.).	
Iva	*Achillea moschata* Jacq.	Do.
Labdanum	*Cistus* spp.	
Lemon-verbena	*Lippia citriodora* HBK.	Do.
Linaloe wood	*Bursera delpechiana* Poiss. and other *Bursera* spp.	
Linden leaves	*Tilia* spp.	Do.
Lovage	*Levisticum officinale* Koch.	
Lungmoss (lungwort)	*Sticta pulmonacea* Ach.	
Maidenhair fern	*Adiantum capillus-veneris* L.	Do.
Maple, mountain	*Acer spicatum* Lam.	
Mimosa (black wattle) flowers	*Acacia decurrens* Willd. var. *dealbata*.	
Mullein flowers	*Verbascum phlomoides* L. or *V. thapsiforme* Schrad.	Do.
Myrrh	*Commiphora molmol* Engl., *C. abyssinica* (Berg) Engl., or other *Commiphora* spp.	
Myrtle leaves	*Myrtus communis* L.	Do.
Oak, English, wood	*Quercus robur* L.	Do.
Oak, white, chips	*Quercus alba* L.	
Oak moss	*Evernia prunastri* (L.) Ach., *E. furfuracea* (L.) Mann, and other lichens.	Finished food thujone.
Olibanum	*Boswellia carteri* Birdw. and other *Boswellia* spp.	
Opopanax (bisabolmyrrh)	*Opopanax chironium* Koch (true opopanax) of *Commiphora erythraea* Engl. var. *Llabrescens*.	
Orris root	*Iris germanica* L. (including its variety *florentina* Dykes) and *I. pallida* Lam.	
Pansy	*Viola tricolor* L.	In alcoholic beverages only.
Passion flower	*Passiflora incarnata* L.	
Patchouly	*Pogostemon cablin* Benth. and *P. heyneanus* Benth.	
Peach leaves	*Prunus persica* (L.) Batsch	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor.
Pennyroyal, American	*Hedeoma pulegioides* (L.) Pers.	
Pennyroyal, European	*Mentha pulegium* L.	
Pine, dwarf, needles and twigs	*Pinus mugo* Turra var. *pumilio* (Haenke) Zenari.	
Pine, Scotch, needles and twigs	*Pinus sylvestris* L.	

Common name	Scientific name	Limitations
Pine, white, bark	*Pinus strobus* L	In alcoholic beverages only.
Pine, white oil	*Pinus palustris* Mill., and other *Pinus* spp	
Poplar buds	*Populus balsamifera* L. (*P. tacamahacca* Mill.), *P. candicans* Ait., or *P. nigra* L.	Do.
Quassia	*Picrasma excelsa* (Sw.) Planch, or *Quassia amara* L.	
Quebracho bark	*Aspidosperma quebracho-blanco* Schlecht, or (*Quebrachia lorentzii* (Griseb)).	*Schinopsis lorentzii* (Griseb.) Engl.
Quillaia (soapbark)	*Quillaja saponaria* Mol	
Red saunders (red sandalwood)	*Pterocarpus santalinus* L	In alcoholic beverages only.
Rhatany root	*Krameria triandra* Ruiz et Pav. or *K. argentea* Mart.	
Rhubarb, garden root	*Rheum rhaponticum* L	Do.
Rhubarb root	*Rheum officinale* Baill., *R. palmatum* L., or other spp. (excepting *R. rhaponticum* L.) or hybrids of *Rheum* grown in China.	
Roselle	*Hibiscus sabdariffa* L	Do.
Rosin (colophony)	*Pinus palustris* Mill., and other *Pinus* spp	Do.
St. Johnswort leaves, flowers, and caulis.	*Hypericum perforatum* L	Hypericin-free alcohol distillate form only; in alcoholic beverages only.
Sandalwood, white (yellow, or East Indian).	*Santalum album* L	
Sandarac	*Tetraclinis articulata* (Vahl.), Mast	In alcoholic beverages only.
Sarsaparilla	*Smilax aristolochiaefolia* Mill., (Mexican sarsaparilla), *S. regelii* Killip et Morton (Honduras sarsaparilla), *S. febrifuga* Kunth (Ecuadorean sarsaparilla), or undetermined *Smilax* spp. (Ecuadorean or Central American sarsaparilla).	
Sassafras leaves	*Sassafras albidum* (Nutt.) Nees	Safrole free.
Senna, Alexandria	*Cassia acutifolia* Delile	
Serpentaria (Virginia snakeroot)	*Aristolochia serpentaria* L	In alcoholic beverages only.
Simaruba bark	*Simaruba amara* Aubl	Do.
Snakeroot, Canadian (wild ginger)	*Asarum canadense* L.	
Spruce needles and twigs	*Picea glauca* (Moench) Voss or *P. mariana* (Mill.) BSP.	
Storax (styrax)	*Liquidambar orientalis* Mill. or *L. styraciflua* L	
Tagetes (marigold)	*Tagetes patula* L., *T. erecta* L., or *T. minuta* L. (*T. glandulifera* Schrank).	As oil only.
Tansy	*Tanacetum vulgare* L	In alcoholic beverages only; finished alcoholic beverage thujone free.[1]
Thistle, blessed (holy thistle)	*Cnicus benedictus* L	In alcoholic beverages only.
Thymus capitatus (Spanish "origanum")	*Thymus capitatus* Hoffmg. et Link.	
Tolu	*Myroxylon balsamum* (L.) Harms	
Turpentine	*Pinus palustris* Mill. and other *Pinus* spp. which yield terpene oils exclusively.	
Valerian rhizome and roots	*Valeriana officinalis* L	
Veronica	*Veronica officinalis* L	Do.
Vervain, European	*Verbena officinalis* L	Do.
Vetiver	*Vetiveria zizanioides* Stapf	Do.
Violet, Swiss	*Viola calcarata* L	
Walnut husks (hulls), leaves, and green nuts.	*Juglans nigra* L. or *J. regia* L	
Woodruff, sweet	*Asperula odorata* L	In alcoholic beverages only.
Yarrow	*Achillea millefolium* L	In beverages only; finished beverage thujone free.[1]
Yerba santa	*Eriodictyon californicum* (Hook. et Arn.) Torr	
Yucca, Joshua-tree	*Yucca brevifolia* Engelm	
Yucca, Mohave	*Yucca schidigera* Roezl ex Ortgies (*Y. mohavensis* Sarg.).	

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[1] As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 14644, Apr. 7, 1978; 49 FR 10104, Mar. 19, 1984]

§ 172.515 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended effect, and otherwise in accordance with all the principles of good manufacturing practice.

(b) They consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, prior-sanctioned for such use, or regulated by an appropriate section in this part.

Acetal; acetaldehyde diethyl acetal.
Acetaldehyde phenethyl propyl acetal.
Acetanisole; 4'-methoxyacetophenone.
Acetophenone; methyl phenyl ketone.
Allyl anthranilate.
Allyl butyrate.
Allyl cinnamate.
Allyl cyclohexaneacetate.
Allyl cyclohexanebutyrate.
Allyl cyclohexanehexanoate.
Allyl cyclohexaneproprionate.
Allyl cyclohexanevalerate.
Allyl disulfide.
Allyl 2-ethylbutyrate.
Allyl hexanoate; allyl caproate.
Allyl *α*-ionone; 1-(2,6,6-trimethyl-2-cyclohexene-1-yl)-1,6-heptadiene-3-one.
Allyl isothiocyanate; mustard oil.
Allyl isovalerate.
Allyl mercaptan; 2-propene-1-thiol.
Allyl nonanoate.
Allyl octanoate.
Allyl phenoxyacetate.
Allyl phenylacetate.
Allyl propionate.
Allyl sorbate; allyl 2,4-hexadienoate.
Allyl sulfide.
Allyl tiglate; allyl *trans*-2-methyl-2-butenoate.
Allyl 10-undecenoate.
Ammonium isovalerate.
Ammonium sulfide.
Amyl alcohol; pentyl alcohol.
Amyl butyrate.
α-Amylcinnamaldehyde.
α-Amylcinnamaldehyde dimethyl acetal.
α-Amylcinnamyl acetate.
α-Amylcinnamyl alcohol.
α-Amylcinnamyl formate.
α-Amylcinnamyl isovalerate.
Amyl formate.
Amyl heptanoate.
Amyl hexanoate.
Amyl octanoate.
Anisole; methoxybenzene.
Anisyl acetate.
Anisyl alcohol; *p*-methoxybenzyl alcohol.
Anisyl butyrate
Anisyl formate.
Anisyl phenylacetate.
Anisyl propionate.
Beechwood creosote.
Benzaldehyde dimethyl acetal.
Benzaldehyde glyceryl acetal; 2-phenyl-*m*-dioxan-5-ol.
Benzaldehyde propylene glycol acetal; 4-methyl-2-phenyl-*m*-dioxolane.
Benzenethiol; thiophenol.
Benzoin; 2-hydroxy-2-phenylacetophenone.
Benzophenone; diphenylketone.
Benzyl acetate.
Benzyl acetoacetate.
Benzyl alcohol.
Benzyl benzoate.
Benzyl butyl ether.
Benzyl butyrate.
Benzyl cinnamate.
Benzyl 2,3-dimethylcrotonate; benzyl methyl tiglate.
Benzyl disulfide; dibenzyl disulfide.
Benzyl ethyl ether.
Benzyl formate.
3-Benzyl-4-heptanone; benzyl dipropyl ketone.
Benzyl isobutyrate.
Benzyl isovalerate.
Benzyl mercaptan; *α*-toluenethiol.
Benzyl methoxyethyl acetal; acetaldehyde benzyl *β*-methoxyethyl acetal.
Benzyl phenylacetate.
Benzyl propionate.
Benzyl salicylate.
Birch tar oil.
Borneol; *d*-camphanol.
Bornyl acetate.
Bornyl formate.
Bornyl isovalerate.
Bornyl valerate.
β-Bourbonene; 1,2,3,3a,3b*β*,4,5,6,6a*β*,6b*α*-deca-hydro-1*α*-isopropyl-3a,-methyl-6-methylene-cyclobuta [1,2:3,4] dicyclopentene.
2-Butanol.
2-Butanone; methyl ethyl ketone.
Butter acids.
Butter esters.
Butyl acetate.
Butyl acetoacetate.
Butyl alcohol; 1-butanol.
Butyl anthranilate.
Butyl butyrate.
Butyl butyryllactate; lactic acid, butyl ester, butyrate.
α-Butylcinnamaldehyde.
Butyl cinnamate.

Butyl 2-decenoate.
Butyl ethyl malonate.
Butyl formate.
Butyl heptanoate.
Butyl hexanoate.
Butyl *p*-hydroxybenzoate.
Butyl isobutyrate.
Butyl isovalerate.
Butyl lactate.
Butyl laurate.
Butyl levulinate.
Butyl phenylacetate.
Butyl propionate.
Butyl stearate.
Butyl sulfide.
Butyl 10-undecenoate.
Butyl valerate.
Butyraldehyde.
Cadinene.
Camphene; 2,2-dimethyl-3-methylenenorbornane.
d-Camphor.
Carvacrol; 2-*p*-cymenol.
Carvacryl ethyl ether; 2-ethoxy-*p*-cymene.
Carveol; *p*-mentha-6,8-dien-2-ol.
4-Carvomenthenol; 1-*p*-menthen-4-ol; 4-terpinenol.
cis Carvone oxide; 1,6-epoxy-*p*-menth-8-en-2-one.
Carvyl acetate.
Carvyl propionate.
β-Caryophyllene.
Caryophyllene alcohol.
Caryophyllene alcohol acetate.
β-Caryophyllene oxide; 4-12,12-trimethyl-9-methylene-5-oxatricylo [8.2.0.0^{4,6}] dodecane.
Cedarwood oil alcohols.
Cedarwood oil terpenes.
1,4-Cineole.
Cinnamaldehyde ethylene glycol acetal.
Cinnamic acid.
Cinnamyl acetate.
Cinnamyl alcohol; 3-phenyl-2-propen-1-ol.
Cinnamyl benzoate.
Cinnamyl butyrate.
Cinnamyl cinnamate.
Cinnamyl formate.
Cinnamyl isobutyrate.
Cinnamyl isovalerate.
Cinnamyl phenylacetate.
Cinnamyl propionate.
Citral diethyl acetal; 3,7-dimethyl-2,6-octadienal diethyl acetal.
Citral dimethyl acetal; 3,7-dimethyl-2,6-octadienal dimethyl acetal.
Citral propylene glycol acetal.
Citronellal; 3,7-dimethyl-6-octenal; rhodinal.
Citronellol; 3,7-dimethyl-6-octen-1-ol; *d*-citronellol.
Citronelloxyacetaldehyde.
Citronellyl acetate.
Citronellyl butyrate.
Citronellyl formate.
Citronellyl isobutyrate.
Citronellyl phenylacetate.
Citronellyl propionate.
Citronellyl valerate.
p-Cresol.
Cuminaldehyde; cuminal; *p*-isopropyl benzaldehyde.
Cyclohexaneacetic acid.
Cyclohexaneethyl acetate.
Cyclohexyl acetate.
Cyclohexyl anthranilate.
Cyclohexyl butyrate.
Cyclohexyl cinnamate.
Cyclohexyl formate.
Cyclohexyl isovalerate.
Cyclohexyl propionate.
p-Cymene.
γ-Decalactone; 4-hydroxy-decanoic acid, γ-lactone.
γ-Decalactone; 5-hydroxy-decanoic acid, δ-lactone.
Decanal dimethyl acetal.
1-Decanol; decylic alcohol.
2-Decenal.
3-Decen-2-one; heptylidene acetone.
Decyl actate.
Decyl butyrate.
Decyl propionate.
Dibenzyl ether.
4,4-Dibutyl-γ-butyrolactone; 4,4-dibutyl-4-hydroxy-butyric acid, γ-lactone.
Dibutyl sebacate.
Diethyl malate.
Diethyl malonate; ethyl malonate.
Diethyl sebacate.
Diethyl succinate.
Diethyl tartrate.
2,5-Diethyltetrahydrofuran.
Dihydrocarveol; 8-*p*-menthen-2-ol; 6-methyl-3-isopropenylcyclohexanol.
Dihydrocarvone.
Dihydrocarvyl acetate.
m-Dimethoxybenzene.
p-Dimethoxybenzene; dimethyl hydroquinone.
2,4-Dimethylacetophenone.
α,α-Dimethylbenzyl isobutyrate; phenyldimethylcarbinyl isobutyrate.
2,6-Dimethyl-5-heptenal.
2,6-Dimethyl octanal; isodecylaldehyde.
3,7-Dimethyl-1-octanol; tetrahydrogeraniol.
α,α-Dimethylphenethyl acetate; benzylpropyl acetate; benzyldimethylcarbinyl acetate.
α,α-Dimethylphenethyl alcohol; dimethylbenzyl carbinol.
α,α-Dimethylphenethyl butyrate; benzyldimethylcarbinyl butyrate.
α,α-Dimethylphenethyl formate; benzyldimethylcarbinyl formate.
Dimethyl succinate.
1,3-Diphenyl-2-propanone; dibenzyl ketone.
delta-Dodecalactone; 5-hydroxydodecanoic acid, deltalactone.
γ-Dodecalactone; 4-hydroxydodecanoic acid γ-lactone.
2-Dodecenal.
Estragole.
p-Ethoxybenzaldehyde.

Ethyl acetoacetate.
Ethyl 2-acetyl-3-phenylpropionate; ethylbenzyl acetoacetate.
Ethyl aconitate, mixed esters.
Ethyl acrylate.
Ethyl *p*-anisate.
Ethyl anthranilate.
Ethyl benzoate.
Ethyl benzoylacetate.
α-Ethylbenzyl butyrate; α-phenylpropyl butyrate.
Ethyl brassylate; tridecanedioic acid cyclic ethylene glycol diester; cyclo 1,13-ethylenedioxytridecan-1,13-dione.
2-Ethylbutyl acetate.
2-Ethylbutyraldehyde.
2-Ethylbutyric acid.
Ethyl cinnamate.
Ethyl crotonate; *trans*-2-butenoic acid ethylester.
Ethyl cyclohexanepropionate.
Ethyl decanoate.
2-Ethylfuran.
Ethyl 2 furanpropionate.
4-Ethylguaiacol; 4-ethyl-2-methoxyphenol.
Ethyl heptanoate.
2-Ethyl-2-heptenal; 2-ethyl-3-butylacrolein.
Ethyl hexanoate.
Ethyl isobutyrate.
Ethyl isovalerate.
Ethyl lactate.
Ethyl laurate.
Ethyl levulinate.
Ethyl maltol; 2-ethyl-3-hydroxy-4H-pyran-4-one.
Ethyl 2-methylbutyrate.
Ethyl myristate.
Ethyl nitrite.
Ethyl nonanoate.
Ethyl 2-nonynoate; ethyl octyne carbonate.
Ethyl octanoate.
Ethyl oleate.
Ethyl phenylacetate.
Ethyl 4-phenylbutyrate.
Ethyl 3-phenylglycidate.
Ethyl 3-phenylpropionate; ethyl hydrocinnamate.
Ethyl propionate.
Ethyl pyruvate.
Ethyl salicylate.
Ethyl sorbate; ethyl 2,4-hexadienoate.
Ethyl tiglate; ethyl *trans*-2-methyl-2-butenoate.
Ethyl undecanoate.
Ethyl 10-undecenoate.
Ethyl valerate.
Eucalpytol; 1,8-epoxy-*p*-menthane; cineole.
Eugenyl acetate.
Eugenyl benzoate.
Eugenyl formate.
Eugenyl methyl ether; 4-allylveratrole; methyl eugenol.
Farnesol; 3,7,11-trimethyl-2,6,10-dodecatrien-1-ol.
d-Fenchone; *d*-1,3,3-trimethyl-2-norbornanone.
Fenchyl alcohol; 1,3,3-trimethyl-2-norbornanol.
Formic acid
(2-Furyl)-2-propanone; furyl acetone.
1-Furyl-2-propanone; furyl acetone.
Fusel oil, refined (mixed amyl alcohols).
Geranyl acetoacetate; *trans*-3,7-dimethyl-2,6-octadien-1-yl acetoacetate.
Geranyl acetone; 6,10-dimethyl-5,9-undecadien-2-one.
Geranyl benzoate.
Geranyl butyrate.
Geranyl formate.
Geranyl hexanoate
Geranyl isobutyrate.
Geranyl isovalerate.
Geranyl phenylacetate.
Geranyl propionate.
Glucose pentaacetate.
Glyceryl monooleate.
Guaiacol; μ-methoxyphenol.
Guaiacyl acetate; μ-methoxyphenyl acetate.
Guaiacyl phenylacetate.
Guaiene; 1,4-dimethyl-7-isopropenyl-Δ9,10-octahydroazulene.
Guaiol acetate; 1,4-dimethyl-7-(α-hydroxyisopropyl)-Δ9,10-octahydroazulene acetate.
γ-Heptalactone; 4-hydroxyheptanoic acid, γ-lactone.
Heptanal; enanthaldehyde.
Heptanal dimethyl acetal.
Heptanal 1,2-glyceryl acetal.
2,3-Heptanedione; acetyl valeryl.
3-Heptanol.
2-Heptanone; methyl amyl ketone.
3-Heptanone; ethyl butyl ketone.
4-Heptanone; dipropyl ketone.
cis-4-Heptenal; *cis*-4-hepten-1-al.
Heptyl acetate.
Heptyl alcohol; enanthic alcohol.
Heptyl butyrate.
Heptyl cinnamate.
Heptyl formate.
Heptyl isobutyrate.
Heptyl octanoate.
1-Hexadecanol; cetyl alcohol.
ω-6-Hexadecenlactone; 16-hydroxy-6-hexadecenoic acid, ω-lactone; ambrettolide.
γ-Hexalactone, 4-hydroxyhexanoic acid, γ-lactone; tonkalide.
Hexanal; caproic aldehyde.
2,3-Hexanedione; acetyl butyryl.
Hexanoic acid; caproic acid.
2-Hexenal.
2-Hexen-1-ol.
3-Hexen-1-ol; leaf alcohol.
2-Hexen-1-yl acetate.
3-Hexenyl isovalerate.
3-Hexenyl 2-methylbutyrate.
3-Hexenyl phenylacetate; *cis*-3-hexenyl phenylacetate.
Hexyl acetate.
2-Hexyl-4-acetoxytetrahydrofuran.
Hexyl alcohol.
Hexyl butyrate.

α-Hexylcinnamaldehyde.
Hexyl formate.
Hexyl hexanoate.
2-Hexylidene cyclopentanone.
Hexyl isovalerate.
Hexyl 2-methylbutyrate.
Hexyl octanoate.
Hexyl phenylacetate; *n*-hexyl phenylacetate.
Hexyl propionate.
Hydroxycitronellal; 3,7-dimethyl-7-hydroxyoctanal.
Hydroxycitronellal diethyl acetal.
Hydroxycitronellal dimethyl acetal.
Hydroxycitronellal; 3,7-dimethyl-1,7-octanediol.
N-(4-Hydroxy-3-methoxybenzyl)-nonanamide; pelargonyl vanillylamide.
5-Hydroxy-4-octanone; butyroin.
4-(*p*-Hydroxyphenyl)-2-butanone; *p*-hydroxybenzyl acetone.
Indole.
α-Ionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one.
β-Ionone; 4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one.
α-Irone; 4-(2,5,6,6-tetramethyl-2-cyclohexene-1-yl)-3-buten-2-one; 6-methylionone.
Isoamyl acetate.
Isoamyl acetoacetate.
Isoamyl alcohol; isopentyl alcohol; 3-methyl-1-butanol.
Isoamyl benzoate.
Isoamyl butyrate.
Isoamyl cinnamate.
Isoamyl formate.
Isoamyl 2-furanbutyrate; α-isoamyl furfurylpropionate.
Isoamyl 2-furanpropionate; α-isoamyl furfurylacetate.
Isoamyl hexanoate.
Isoamyl isobutyrate.
Isoamyl isovalerate.
Isoamyl laurate.
Isoamyl-2-methylbutyrate; isopentyl-2-methylbutyrate.
Isoamyl nonanoate.
Isoamyl octanoate.
Isoamyl phenylacetate.
Isoamyl propionate.
Isoamyl pyruvate.
Isoamyl salicylate.
Isoborneol.
Isobornyl acetate.
Isobornyl formate.
Isobornyl isovalerate.
Isobornyl propionate.
Isobutyl acetate.
Isobutyl acetoacetate.
Isobutyl alcohol.
Isobutyl angelate; isobutyl *cis*-2-methyl-2-butenoate.
Isobutyl anthranilate.
Isobutyl benzoate.
Isobutyl butyrate.
Isobutyl cinnamate.
Isobutyl formate.
Isobutyl 2-furanpropionate.
Isobutyl heptanoate.
Isobutyl hexanoate.
Isobutyl isobutyrate.
α-Isobutylphenethyl alcohol; isobutyl benzyl carbinol; 4-methyl-1-phenyl-2-pentanol.
Isobutyl phenylacetate.
Isobutyl propionate.
Isobutyl salicylate.
2-Isobutylthiazole.
Isobutyraldehyde.
Isobutyric acid.
Isoeugenol; 2-methoxy-4-propenylphenol.
Isoeugenyl acetate.
Isoeugenyl benzyl ether; benzyl isoeugenol.
Isoeugenyl ethyl ether; 2-ethoxy-5-propenyl-anisole; ethyl isoeugenol.
Isoeugenyl formate.
Isoeugenyl methyl ether; 4-propenylveratrole; methyl isoeugenol.
Isoeugenyl phenylacetate.
Isojasmone; mixture of 2-hexylidenecyclopentanone and 2-hexyl-2-cyclopenten-1-one.
α-Isomethylionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-methyl-3-buten-2-one; methyl γ-ionone.
Isopropyl acetate.
p-Isopropylacetophenone.
Isopropyl alcohol; isopropanol.
Isopropyl benzoate.
p-Isopropylbenzyl alcohol; cuminic alcohol; *p*-cymen-7-ol.
Isopropyl butyrate.
Isopropyl cinnamate.
Isopropyl formate.
Isopropyl hexanoate.
Isopropyl isobutyrate.
Isopropyl isovalerate.
p-Isopropylphenylacetaldehyde; *p*-cymen-7-carboxaldehyde.
Isopropyl phenylacetate.
3-(*p*-Isopropylphenyl)-propionaldehyde; *p*-isopropylhydrocinnamaldehyde; cuminyl acetaldehyde.
Isopropyl propionate.
Isopulegol; *p*-menth-8-en-3-ol.
Isopulegone; *p*-menth-8-en-3-one.
Isopulegyl acetate.
Isoquinoline.
Isovaleric acid.
cis-Jasmone; 3-methyl-2-(2-pentenyl)-2-cyclopenten-1-one.
Lauric aldehyde; dodecanal.
Lauryl acetate.
Lauryl alcohol; 1-dodecanol.
Lepidine; 4-methylquinoline.
Levulinic acid.
Linalool oxide; *cis*- and *trans*-2-vinyl-2-methyl-5-(1′-hydroxy-1′-methylethyl) tetrahydrofuran.
Linalyl anthranilate; 3,7-dimethyl-1,6-octadien-3-yl anthranilate.
Linalyl benzoate.
Linalyl butyrate.

Linalyl cinnamate.
Linalyl formate.
Linalyl hexanoate.
Linalyl isobutyrate.
Linalyl isovalerate.
Linalyl octanoate.
Linalyl propionate.
Maltol; 3-hydroxy-2-methyl-4H-pyran-4-one.
Menthadienol; *p*-mentha-1,8(10)-dien-9-ol.
p- Mentha-1,8-dien-7-ol; perillyl alcohol.
Menthadienyl acetate; *p*-mentha-1,8(10)-dien-9-yl acetate.
p-Menth-3-en-1-ol.
1-*p*-Menthen--9-yl acetate; *p*-menth-1-en-9-yl acetate.
Menthol; 2-isopropyl-5-methylcyclohexanol.
Menthone; *p*-menthan-3-one.
Menthyl acetate; *p*- menth-3-yl acetate.
Menthyl isovalerate; *p*-menth-3-yl isovalerate.
o-Methoxybenzaldehyde.
p- Methoxybenzaldehyde; *p*-anisaldehyde.
o-Methoxycinnamaldehyde.
2-Methoxy-4-methylphenol; 4-methylguaiacol; 2-methoxy-*p*-cresol.
4-(*p*-Methoxyphenyl)-2-butanone; anisyl acetone.
1-(4-Methoxyphenyl)-4-methyl-1-penten-3-one; methoxystyryl isopropyl ketone.
1-(*p*-Methoxyphenyl)-1-penten-3-one; α-methylanisylidene acetone; ethone.
1-(*p*-Methoxyphenyl)-2-propanone; anisylmethyl ketone; anisic ketone.
2-Methoxy-4-vinylphenol; *p*-vinylguaiacol.
Methyl acetate.
4′-Methylacetophenone; *p*-methylacetophenone; methyl *p*-tolyl ketone.
2-Methylallyl butyrate; 2-methyl-2-propenl-yl butyrate.
Methyl anisate.
o-Methylanisole; *o*-cresyl methyl ether.
p-Methylanisole; *p*-cresyl methyl ether; *p*-methoxytoluene.
Methyl benzoate.
Methylbenzyl acetate, mixed *o*-,*m*-,*p*-.
α-Methylbenzyl acetate; styralyl acetate.
α-Methylbenzyl alcohol; styralyl alcohol.
α-Methylbenzyl butyrate; styralyl butyrate.
α-Methylbenzyl isobutyrate; styralyl isobutyrate.
α-Methylbenzyl formate; styralyl formate.
α-Methylbenzyl propionate; styralyl propionate.
2-Methyl-3-buten-2-ol.
2-Methylbutyl isovalerate.
Methyl *p*-*tert*-butylphenylacetate.
2-Methylbutyraldehyde; methyl ethyl acetaldehyde.
3-Methylbutyraldehyde; isovaleraldehyde.
Methyl butyrate.
2-Methylbutyric acid.
α-Methylcinnamaldehyde.
p-Methylcinnamaldehyde.
Methyl cinnamate.
2-Methyl-1,3-cyclohexadiene.
Methylcyclopentenolone; 3-methylcyclopentane-1,2-dione.
Methyl disulfide; dimethyl disulfide.
Methyl ester of rosin, partially hydrogenated (as defined in § 172.615); methyl dihydroabietate.
Methyl heptanoate.
2-Methylheptanoic acid.
6-Methyl-3,5-heptadien-2-one.
Methyl-5-hepten-2-ol.
6-Methyl-5-hepten-2-one.
Methyl hexanoate.
Methyl 2-hexanoate.
Methyl *p*-hydroxybenzoate; methylparaben.
Methyl α-ionone; 5-(2,6,6-trimethyl-2-cyclohexen-1-yl)-4-penten-3-one.
Methyl β-ionone; 5-(2,6,6-trimethyl-1-cyclohexen-1-yl)-4-penten-3-one.
Methyl Δ-ionone; 5-(2,6,6-trimethyl-3-cyclohexen-1-yl-)-4-penten-3-one.
Methyl isobutyrate.
2-Methyl-3-(*p*-isopropylphenyl)-propionaldehyde; α-methyl-*p*-isopropylhydro- cinnamal- dehyde; cyclamen aldehyde.
Methyl isovalerate.
Methyl laurate.
Methyl mercaptan; methanethiol.
Methyl *o*-methoxybenzoate.
Methyl *N*-methylanthranilate; dimethyl anthranilate.
Methyl 2-methylbutyrate.
Methyl 2-methylthiopropionate.
Methyl 4-methylvalerate.
Methyl myristate.
Methyl β-naphthyl ketone; 2′-acetonaphthone.
Methyl nonanoate.
Methyl 2-nonenoate.
Methyl 2-nonynoate; methyloctyne carbonate.
2-Methyloctanal; methyl hexyl acetaldehyde.
Methyl octanoate.
Methyl 2-octynoate; methyl heptine carbonate.
4-Methyl-2,3-pentanedione; acetyl isobutyryl.
4-Methyl-2-pentanone; methyl isobutyl ketone.
β-Methylphenethyl alcohol; hydratropyl alcohol.
Methyl phenylacetate.
3-Methyl-4-phenyl-3-butene-2-one.
2-Methyl-4-phenyl-2-butyl acetate; dimethylphenylethyl carbinyl acetate.
2-Methyl-4-phenyl-2-butyl isobutyrate; dimethylphenyl ethylcarbinyl isobutyrate.
3-Methyl-2-phenylbutyraldehyde; α-isopropyl phenylacetaldehyde.
Methyl 4-phenylbutyrate.
4-Methyl-1-phenyl-2-pentanone; benzyl isobutyl ketone.
Methyl 3-phenylpropionate; methyl hydrocinnamate.
Methyl propionate.
3-Methyl-5-propyl-2-cyclohexen-1-one.
Methyl sulfide.
3-Methylthiopropionaldehyde; methional.

2-Methyl-3-tolylpropionaldehyde, mixed *o*-, *m*-, *p*-.
2-Methylundecanal; methyl nonyl acetaldehyde.
Methyl 9-undecenoate.
Methyl 2-undecynoate; methyl decyne carbonate.
Methyl valerate.
2-Methylvaleric acid.
Myrcene; 7-methyl-3-methylene-1,6-octadiene.
Myristaldehyde; tetradecanal.
d-Neomenthol; 2-isopropyl-5-methylcyclohexanol.
Nerol; *cis*-3,7-dimethyl-2,6-octadien-1-ol.
Nerolidol; 3,7,11-trimethyl-1,6,10-dodecatrien-3-ol.
Neryl acetate.
Neryl butyrate.
Neryl formate.
Neryl isobutyrate.
Neryl isovalerate.
Neryl propionate.
2,6-Nonadien-1-ol.
γ-Nonalactone; 4-hydroxynonanoic acid, γ-lactone; aldehyde C-18.
Nonanal; pelargonic aldehyde.
1,3-Nonanediol acetate, mixed esters.
Nonanoic acid; pelargonic acid.
2-Nonanone; methylheptyl ketone.
3-Nonanon-1-yl acetate; 1-hydroxy-3-nonanone acetate.
Nonyl acetate.
Nonyl alcohol; 1-nonanol.
Nonyl octanoate.
Nonyl isovalerate.
Nootkatone; 5,6-dimethyl-8-isopropenyl-bicyclo[4,4,0]-dec-1-en-3-one.
Ocimene; *trans*-β-ocimene; 3,7-dimethyl-1,3,6-octatriene.
γ-Octalactone; 4-hydroxyoctanoic acid, γ-lactone.
Octanal; caprylaldehyde.
Octanal dimethyl acetal.
1-Octanol; octyl alcohol.
2-Octanol.
3-Octanol.
2-Octanone; methyl hexyl ketone.
3-Octanone; ethyl amyl ketone.
3-Octanon-1-ol.
1-Octen-3-ol; amyl vinyl carbinol.
1-Octen-3-yl acetate.
Octyl acetate.
3-Octyl acetate.
Octyl butyrate.
Octyl formate.
Octyl heptanoate.
Octyl isobutyrate.
Octyl isovalerate.
Octyl octanoate.
Octyl phenylacetate.
Octyl propionate.
ω-Pentadecalactone; 15-hydroxypentadecanoic acid, ω-lactone; pentadecanolide; angelica lactone.
2,3-Pentanedione; acetyl propionyl.
2-Pentanone; methyl propyl ketone.
4-Pentenoic acid.
1-Penten-3-ol.
Perillaldehyde; 4-isopropenyl-1-cyclohexene-1-carboxaldehyde;*p*-mentha-1,8-dien-7-al.
Perillyl acetate; *p*-mentha-1,8-dien-7-yl acetate.
α-Phellandrene; *p*-mentha-1,5-diene.
Phenethyl acetate.
Phenethyl alcohol; β-phenylethyl alcohol.
Phenethyl anthranilate.
Phenethyl benzoate.
Phenethyl butyrate.
Phenethyl cinnamate.
Phenethyl formate.
Phenethyl isobutyrate.
Phenethyl isovalerate.
Phenethyl 2-methylbutyrate.
Phenethyl phenylacetate.
Phenethyl propionate.
Phenethyl salicylate.
Phenethyl senecioate; phenethyl 3,3-dimethylacrylate.
Phenethyl tiglate.
Phenoxyacetic acid.
2-Phenoxyethyl isobutyrate.
Phenylacetaldehyde; α-toluic aldehyde.
Phenylacetaldehyde 2,3-butylene glycol acetal.
Phenylacetaldehyde dimethyl acetal.
Phenylacetaldehyde glyceryl acetal.
Phenylacetic acid; α-toluic acid.
4-Phenyl-2-butanol; phenylethyl methyl carbinol.
4-Phenyl-3-buten-2-ol; methyl styryl carbinol.
4-Phenyl-3-buten-2-one.
4-Phenyl-2-butyl acetate; phenylethyl methyl carbinyl acetate.
1-Phenyl-3-methyl-3-pentanol; phenylethyl methyl ethyl carbinol.
1-Phenyl-1-propanol; phenylethyl carbinol.
3-Phenyl-1-propanol; hydrocinnamyl alcohol.
2-Phenylpropionaldehyde; hydratropaldehyde.
3-Phenylpropionaldehyde; hydrocinnamaldehyde.
2-Phenylpropionalde-hyde dimethyl acetal; hydratropic aldehyde dimethyl acetal.
3-Phenylpropionic acid; hydrocinnamic acid.
3-Phenylpropyl acetate.
2-Phenylpropyl butyrate.
3-Phenylpropyl cinnamate.
3-Phenylpropyl formate.
3-Phenylpropyl hexanoate.
2-Phenylpropyl isobutyrate.
3-Phenylpropyl isobutyrate.
3-Phenylpropyl isovalerate.
3-Phenylpropyl propionate.
2-(3-Phenylpropyl)-tetrahydrofuran.
α-Pinene; 2-pinene.
β-Pinene; 2(10)-pinene.
Pine tar oil.
Pinocarveol; 2(10)-pinen-3-ol.
Piperidine.

Piperine.
d-Piperitone; *p*-menth-1-en-3-one.
Piperitenone; *p*-mentha-1,4(8)-dien-3-one.
Piperitenone oxide; 1,2-epoxy-*p*-menth-4-(8)-en-3-one.
Piperonyl acetate; heliotropyl acetate.
Piperonyl isobutyrate.
Polylimonene.
Polysorbate 20; polyoxyethylene (20) sorbitan monolaurate.
Polysorbate 60; polyoxyethylene (20) sorbitan monostereate.
Polysorbate 80; polyoxyethylene (20) sorbitan monooleate.
Potassium acetate.
Propenylguaethol; 6-ethoxy-*m*-anol.
Propionaldehyde.
Propyl acetate.
Propyl alcohol; 1-propanol.
p-Propyl anisole; dihydroanethole.
Propyl benzoate.
Propyl butyrate.
Propyl cinnamate.
Propyl disulfide.
Propyl formate.
Propyl 2-furanacrylate.
Propyl heptanoate.
Propyl hexanoate.
Propyl *p*-hydroxybenzoate; propylparaben.
3-Propylidenephthalide.
Propyl isobutyrate.
Propyl isovalerate.
Propyl mercaptan.
α-Propylphenethyl alcohol.
Propyl phenylacetate.
Propyl propionate.
Pulegone; *p*-menth-4(8)-en-3-one.
Pyridine.
Pyroligneous acid extract.
Pyruvaldehyde.
Pyruvic acid.
Rhodinol, 3,7-dimethyl-7-octen-1-ol; *l*-citronellol.
Rhodinyl acetate.
Rhodinyl butyrate.
Rhodinyl formate.
Rhodinyl isobutyrate.
Rhodinyl isovalerate.
Rhodinyl phenylacetate.
Rhodinyl propionate.
Rum ether; ethyl oxyhydrate.
Salicylaldehyde.
Santalol, α and β.
Santalyl acetate.
Santalyl phenylacetate.
Skatole.
Sorbitan monostearate.
Styrene.
Sucrose octaacetate.
α-Terpinene.
γ-Terpinene.
α-Terpineol; *p*-menth-1-en-8-ol.
β-Terpineol.
Terpinolene; *p*-menth-1,4(8)-diene.
Terpinyl acetate.
Terpinyl anthranilate.
Terpinyl butyrate.
Terpinyl cinnamate.
Terpinyl formate.
Terpinyl isobutyrate.
Terpinyl isovalerate.
Terpinyl propionate.
Tetrahydrofurfuryl acetate.
Tetrahydrofurfuryl alcohol.
Tetrahydrofurfuryl butyrate.
Tetrahydrofurfuryl propionate.
Tetrahydro-pseudo-ionone; 6,10-dimethyl-9-undecen-2-one.
Tetrahydrolinalool; 3,7-dimethyloctan-3-ol.
Tetramethyl ethylcyclohexenone; mixture of 5-ethyl-2,3,4,5-tetramethyl-2-cyclohexen-1-one and 5-ethyl-3,4,5,6-tetramethyl-2-cyclohexen-1-one.
2-Thienyl mercaptan; 2-thienylthiol.
Thymol.
Tolualdehyde glyceryl acetal, mixed *o, m, p*.
Tolualdehydes, mixed *o, m, p*.
p-Tolylacetaldehyde.
o-Tolyl acetate; *o*-cresyl acetate.
p-Tolyl acetate; *p*-cresyl acetate.
4-(*p*-Tolyl)-2-butanone; *p*-methylbenzylacetone.
p-Tolyl isobutyrate.
p-Tolyl laurate.
p-Tolyl phenylacetate.
2-(*p*-Tolyl)-propionaldehyde; *p*-methylhydratropic aldehyde.
Tributyl acetylcitrate.
2-Tridecenal.
2,3-Undecadione; acetyl nonyryl.
γ-Undecalactone; 4-hydroxyundecanoic acid γ-lactone; peach aldehyde; aldehyde C-14.
Undecenal.
2-Undecanone; methyl nonyl ketone.
9-Undecenal; undecenoic aldehyde.
10-Undecenal.
Undecen-1-ol; undecylenic alcohol.
10-Undecen-1-yl acetate.
Undecyl alcohol.
Valeraldehyde; pentanal.
Valeric acid; pentanoic acid.
Vanillin acetate; acetyl vanillin.
Veratraldehyde.
Verbenol; 2-pinen-4-ol.
Zingerone; 4-(4-hydroxy-3-methoxyphenyl)-2-butanone.

(c) Δ-Decalactone and Δ-dodecalactone when used separately or in combination in oleomargarine are used at levels not to exceed 10 parts per million and 20 parts per million, respectively, in accordance with § 166.110 of this chapter.

(d) BHA (butylated hydroxyanisole) may be used as an antioxidant in flavoring substances whereby the additive does not exceed 0.5 percent of the essential (volatile) oil content of the flavoring substance.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 23148, May 6, 1977; 43 FR 19843, May 9, 1978; 45 FR 22915, Apr. 4, 1980; 47 FR 27810, June 25, 1982; 48 FR 10812, Mar. 15, 1983; 48 FR 51907, Nov. 15, 1983; 49 FR 5747, Feb. 15, 1984; 50 FR 42932, Oct. 23, 1985]

§ 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

The food additive "cocoa with dioctyl sodium sulfosuccinate for manufacturing," conforming to § 163.117 of this chapter and § 172.810, is used or intended for use as a flavoring substance in dry beverage mixes whereby the amount of dioctyl sodium sulfosuccinate does not exceed 75 parts per million of the finished beverage. The labeling of the dry beverage mix shall bear adequate directions to assure use in compliance with this section.

§ 172.530 Disodium guanylate.

Disodium guanylate may be safely used as a flavor enhancer in foods, at a level not in excess of that reasonably required to produce the intended effect.

§ 172.535 Disodium inosinate.

The food additive disodium inosinate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the disodium salt of inosinic acid, manufactured and purified so as to contain no more than 150 parts per million of soluble barium in the compound disodium inosinate with seven and one-half molecules of water of crystallization.

(b) The food additive is used as a flavoring adjuvant in food.

§ 172.560 Modified hop extract.

The food additive modified hop extract may be safely used in beer in accordance with the following prescribed conditions:

(a) The food additive is used or intended for use as a flavoring agent in the brewing of beer.

(b) The food additive is manufactured by one of the following processes:

(1) The additive is manufactured from a hexane extract of hops by simultaneous isomerization and selective reduction in an alkaline aqueous medium with sodium borohydride, whereby the additive meets the following specifications:

(i) A solution of the food additive solids is made up in approximately 0.012 *n* alkaline methyl alcohol (6 milliliters of 1 *n* sodium hydroxide diluted to 500 milliliters with methyl alcohol) to show an absorbance at 253 millimicrons of 0.6 to 0.9 per centimeter. (This absorbance is obtained by approximately 0.03 milligram solids per milliliter.) The ultraviolet absorption spectrum of this solution exhibits the following characteristics: An absorption peak at 253 millimicrons; no absorption peak at 325 to 330 millimicrons; the absorbance at 268 millimicrons does not exceed the absorbance at 272 millimicrons.

(ii) The boron content of the food additive does not exceed 310 parts per million (0.0310 percent), calculated as boron.

(2) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, and methyl alcohol as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, and 250 parts per million of methyl alcohol. The light petroleum spirits and benzene solvents shall comply with the specifications in § 172.250 except that the boiling point range for light petroleum spirits is 150°F-300°F.

(3) The additive is manufactured from hops by a sequence of extractions and fractionations, using methylene chloride, hexane, and methyl alcohol as solvents, followed by isomerization by sodium hydroxide treatment. Residues of the solvents in the modified hop extract shall not exceed 5 parts per million of methylene chloride, 25 parts per million of hexane, and 100 parts per million of methyl alcohol.

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, *n*-butyl alcohol, and ethyl acetate as solvents, followed by isomeriza-

tion by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million of *n*-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in § 172.250 except that the boiling point range for light petroleum spirits is 150° F to 300° F.

(5) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the following solvents: Ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene, and water; followed by isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene and a further sequence of extractions and fractionations using one or more of the solvents set forth in this paragraph. Residues of the solvents in the modified hop extract shall not exceed 125 parts per million of hexane; 150 parts per million of ethylene dichloride, methylene chloride, or trichloroethylene, or 250 parts per million of isopropyl alcohol or methyl alcohol.

(6) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by: Hydrogenation using palladium as a catalyst in methyl alcohol, ethyl alcohol, or isopropyl alcohol acidified with hydrochloric or sulfuric acid; oxidation with peracetic acid; isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene (alternatively, the hydrogenation and isomerization steps may be performed in reverse order); and a further sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section.

(7) The additive is manufactured from hops as set forth in paragraph (b)(6) of this section followed by reduction with sodium borohydride in aqueous alkaline methyl alcohol, and a sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section, and a boron content level not in excess of 300 parts per million (0.0300 percent), calculated as boron.

(8) The additive is manufactured from hops as a nonisomerizable nonvolatile hop resin by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by a sequence of aqueous extractions and removal of nonaqueous solvents to less than 0.5 percent. The additive is added to the wort before or during cooking in the manufacture of beer.

§ 172.575 Quinine.

Quinine, as the hydrochloride salt or sulfate salt, may be safely used in food in accordance with the following conditions:

Uses	Limitations
In carbonated beverages as a flavor.	Not to exceed 83 parts per million, as quinine. Label shall bear a prominent declaration of the presence of quinine either by the use of the word "quinine" in the name of the article or through a separate declaration.

§ 172.580 Safrole-free extract of sassafras.

The food additive safrole-free extract of sassafras may be safely used in accordance with the following prescribed conditions:

(a) The additive is the aqueous extract obtained from the root bark of the plant *Sassafras albidum* (Nuttall) Nees (Fam. Lauraceae).

(b) It is obtained by extracting the bark with dilute alcohol, first concentrating the alcoholic solution by vacuum distillation, then diluting the concentrate with water and discarding the oily fraction.

(c) The purified aqueous extract is safrole-free.

(d) It is used as a flavoring in food.

§ 172.585 Sugar beet extract flavor base.

Sugar beet extract flavor base may be safely used in food in accordance with the provisions of this section.

(a) Sugar beet extract flavor base is the concentrated residue of soluble sugar beet extractives from which sugar and glutamic acid have been recovered, and which has been subjected to ion exchange to minimize the concentration of naturally occurring trace minerals.

(b) It is used as a flavor in food.

§ 172.590 Yeast-malt sprout extract.

Yeast-malt sprout extract, as described in this section, may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by partial hydrolysis of yeast extract (derived from *Saccharomyces cereviseae, Saccharomyces fragilis,* or *Candida utilis*) using the sprout portion of malt barley as the source of enzymes. The additive contains a maximum of 6 percent 5′ nucleotides by weight.

(b) The additive may be used as a flavor enhancer in food at a level not in excess of that reasonably required to produce the intended effect.

Subpart G—Gums, Chewing Gum Bases and Related Substances

§ 172.610 Arabinogalactan.

Arabinogalactan may be safely used in food in accordance with the following conditions:

(a) Arabinogalactan is a polysaccharide extracted by water from Western larch wood, having galactose units and arabinose units in the approximate ratio of six to one.

(b) It is used in the following foods in the minimum quantity required to produce its intended effect as an emulsifier, stabilizer, binder, or bodying agent: Essential oils, nonnutritive sweeteners, flavor bases, nonstandardized dressings, and pudding mixes.

§ 172.615 Chewing gum base.

The food additive chewing gum base may be safely used in the manufacture of chewing gum in accordance with the following prescribed conditions:

(a) The food additive consists of one or more of the following substances that meet the specifications and limitations prescribed in this paragraph, used in amounts not to exceed those required to produce the intended physical or other technical effect.

MASTICATORY SUBSTANCES

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
Sapotaceae:	
Chicle	Manikara zapotilla Gilly and Manikara chicle Gilly
Chiquibul	Manikara zapotilla Gilly.
Crown gum	Manikara zapotilla Gilly and Manikara chicle Gilly.
Gutta hang kang	Palaquium leiocarpum Boerl. and Palaquium oblongifolium Burck.
Massaranduba balata (and the solvent-free resin extract of Massaranduba balata)	Manikara huberi (Ducke) Chevalier.
Massaranduba chocolate	Manikara solimoesensis Gilly.
Nispero	Manikara zapotilla Gilly and Manikara chicle Gilly.
Rosidinha (rosadinha)	Micropholis (also known as Sideroxylon) spp.
Venezuelan chicle	Manikara williamsii Standley and related spp.
Apocynaceae:	
Jelutong	Dyera costulata Hook, F. and Dyera lowii Hook, F.
Leche caspi (sorva)	Couma macrocarpa Barb. Rodr.
Pendare	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Perillo	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Moraceae:	
Leche de vaca	Brosimum utile (H.B.K.) Pittier and Poulsenia spp.; also Lacmellea standleyi (Woodson), Monachino (Apocynaceae).
Niger gutta	Ficus platyphylla Del.
Tunu (tuno)	Castilla fallax Cook.
Euphorbiaceae:	
Chilte	Cnidoscolus (also known as Jatropha) elasticus Lundell and Cnidoscolus tepiquensis (Cost. and Gall.) McVaugh.

MASTICATORY SUBSTANCES—Continued

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
Natural rubber (smoked sheet and latex solids)	Hevea brasiliensis.

Synthetic	Specifications
Butadiene-styrene rubber	Basic polymer.
Isobutylene-isoprene copolymer (butyl rubber)	Do.
Paraffin	Synthesized by Fischer-Tropsch process from carbon monoxide and hydrogen which are catalytically converted to a mixture of paraffin hydrocarbon. Lower molecular weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. The product has a congealing point of 93°-99° C as determined by ASTM method D938-71 (Reapproved 1981), "Standard Test Method for Congealing Point of Petroleum Waxes, Including Petrolatum," a maximum oil content of 0.5 percent as determined by ASTM method D721-56T, "Tentative Method of Test for Oil Content of Petroleum Waxes," and an absorptivity of less than 0.01 at 290 millimicrons in decahydronaphthalene at 88° C as determined by ASTM method D2008-80, "Standard Test Method for Ultraviolet Absorbance and Absorptivity of Petroleum Products," which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.
Petroleum wax	Complying with § 172.886.
Petroleum wax synthetic	Complying with § 172.888.
Polyethylene	Molecular weight 2,000-21,000.
Polyisobutylene	Minimum molecular weight 37,000 (Flory).
Polyvinyl acetate	Molecular weight, minimum 2,000.

PLASTICIZING MATERIALS (SOFTENERS)

Glycerol ester of partially dimerized rosin	Having an acid number of 3-8, a drop-softening point of 109° C-119° C, and a color of M or paler.
Glycerol ester of partially hydrogenated gum or wood rosin.	Having an acid number of 3-10, a drop-softening point of 79° C-88° C, and a color of N or paler.
Glycerol ester of polymerized rosin	Having an acid number of 3-12, a melting-point range 80° C-126° C, and a color of M or paler.
Glycerol ester of gum rosin	Having an acid number of 5-9, a drop-softening point of 88° C-96° C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of tall oil rosin	Having an acid number of 2-12, a softening point (ring and ball) of 80°-88° C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of wood rosin	Having an acid number of 3-9, a drop-softening point of 88° C-96° C, and a color of N or paler. The ester is purified by steam stripping.
Lanolin	
Methyl ester of rosin, partially hydrogenated	Having an acid number of 4-8, a refractive index of 1.5170-1.5205 at 20° C, and a viscosity of 23-66 poises at 25° C. The ester is purified by steam stripping.
Pentaerythritol ester of partially hydrogenated gum or wood resin.	Having an acid number of 7-18, a drop-softening point of 102° C-110° C, and a color of K or paler.
Pentaerythritol ester of gum or wood rosin	Having an acid number of 6-16, a drop-softening point of 109° C-116° C, and a color of M or paler.
Rice bran wax	Complying with § 172.890.
Stearic acid	Complying with § 172.860.
Sodium and potassium stearates	Complying with § 172.863.

TERPENE RESINS

Synthetic resin	Consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirit solution.
Natural resin	Consisting of polymers of α-pinene; softening point minimum 155° C, determined by U.S.P. closed-capillary method, United States Pharmacopeia XX (1980) (page 961).

MASTICATORY SUBSTANCES—Continued

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
ANTIOXIDANTS	
Butylated hydroxyanisole	Not to exceed antioxidant content of 0.1% when used alone or in any combination.
Butylated hydroxytoluene	Do.
Propyl gallate	Do.
MISCELLANEOUS	
Sodium sulfate	Reaction-control agent in synthetic polymer production.
Sodium sulfide	

(b) In addition to the substances listed in paragraph (a) of this section, chewing gum base may also include substances generally recognized as safe in food.

(c) To assure safe use of the additive, in addition to the other information required by the act, the label and labeling of the food additive shall bear the name of the additive, "chewing gum base." As used in this paragraph, the term "chewing gum base" means the manufactured or partially manufactured nonnutritive masticatory substance comprised of one or more of the ingredients named and so defined in paragraph (a) of this section.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 56051, Aug. 22, 1980; 49 FR 5747, Feb. 15, 1984; 49 FR 10105, Mar. 19, 1984]

§ 172.620 Carrageenan.

The food additive carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction from the following members of the families Gigartinaceae and Solieriaceae of the class Rodophyceae (red seaweed):

Chondrus crispus.
Chondrus ocellatus.
Eucheuma cottonii.
Eucheuma spinosum.
Gigartina acicularis.
Gigartina pistillata.
Gigartina radula.
Gigartina stellata.

(b) The food additive conforms to the following conditions:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 20 percent to 40 percent on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, carrageenan.

§ 172.623 Carrageenan with polysorbate 80.

Carrageenan otherwise meeting the definition and specifications of § 172.620 (a) and (b) and salts of carrageenan otherwise meeting the definition of § 172.626(a) may be safely produced with the use of polysorbate 80 meeting the specifications and requirements of § 172.840 (a) and (b) in accordance with the following prescribed conditions:

(a) The polysorbate 80 is used only to facilitate separation of sheeted carrageenan and salts of carrageenan from drying rolls.

(b) The carrageenan and salts of carrageenan contain not more than 5 percent by weight of polysorbate 80, and the final food containing the additives contains polysorbate 80 in an amount not to exceed 500 parts per million.

(c) The carrageenan and salts of carrageenan so produced are used only in producing foods in gel form and only for the purposes defined in §§ 172.620(c) and 172.626(b), respectively.

(d) The carrageenan and salts of carrageenan so produced are not used in foods for which standards of identity exist unless the standards provide for the use of carrageenan, or salts of carrageenan, combined with polysorbate 80.

(e) The carrageenan and salts of carrageenan produced in accordance with this section, and foods containing the same, in addition to the other requirements of the Act, are labeled to show the presence of polysorbate 80, and the label or labeling of the carrageenan and salts of carrageenan so produced bear adequate directions for use.

§ 172.626 Salts of carrageenan.

The food additive salts of carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of carrageenan, meeting the provisions of § 172.620, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of carrageenan to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., "sodium carrageenan", "potassium carrageenan", etc.

§ 172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction of furcellaria fastigiata of the class Rodophyceae (red seaweed).

(b) The food additive conforms to the following:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

§ 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of furcelleran, meeting the provisions of § 172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., "sodium furcelleran", "potassium furcelleran", etc.

§ 172.695 Xanthan gum.

The food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris.*

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75° F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75° F and 150° F is in the range of 1.02 to 1.45.

(3) Positive for xanthan gum when subjected to the following procedure:

LOCUST BEAN GUM GEL TEST

Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide to be tested. Add the blend slowly (approximately ½ minute) at the point of maximum agitation to a stirred solution of 200 milliliters of distilled water previously heated to 80° C in a 400-milliliter beaker. Continue mechanical stirring until the mixture is in solution, but stir for a minimum time of 30 minutes. Do not allow the water temperature to drop below 60° C.

Set the beaker and its contents aside to cool in the absence of agitation. Allow a minimum time of 2 hours for cooling. Examine the cooled beaker contents for a firm rubbery gel formation after the temperature drops below 40° C.

In the event that a gel is obtained, make up a 1 percent solution of the polysaccharide to be tested in 200 milliliters of distilled water previously heated to 80° C (omit the locust bean gum). Allow the solution to cool without agitation as before. Formation of a gel on cooling indicates that the sample is a gelling polysaccharide and not xanthan gum.

Record the sample as "positive" for xanthan gum if a firm, rubbery gel forms in the presence of locust bean gum but not in its absence. Record the sample as "negative" for xanthan gum if no gel forms or if a soft or brittle gel forms both with locust bean gum and in a 1 percent solution of the sample (containing no locust bean gum).

(4) Positive for xanthan gum when subjected to the following procedure:

PYRUVIC ACID TEST

Pipet 10 milliliters of an 0.6 percent solution of the polysaccharide in distilled water (60 milligrams of water-soluble gum) into a 50-milliliter flask equipped with a standard taper glass joint. Pipet in 20 milliliters of 1*N* hydrochloric acid. Weigh the flask. Reflux the mixture for 3 hours. Take precautions to avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenylhydrazine reagent (0.5 percent in 2*N* hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 375 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note "positive" for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and "negative" for xanthan gum if the sample contains less than 1.5 percent of pyruvic acid by weight.

(e) The additive is used or intended for use in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer in foods for which standards of identity established under section 401 of the Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Act, the name of the additive and the designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

Subpart H—Other Specific Usage Additives

§ 172.710 Adjuvants for pesticide use dilutions.

The following surfactants and related adjuvants may be safely added to pesticide use dilutions by a grower or applicant prior to application to the growing crop:

n-Alkyl (C_8-C_{18}) amine acetate, where the alkyl groups (C_8-C_{18}) are derived from coconut oil, as a surfactant in emulsifier blends at levels not in excess of 5 percent by weight of the emulsifier blends that are added to herbicides for application to corn and sorghum.

Di-*n*-alkyl (C_8-C_{18}) dimethyl ammonium chloride, where the alkyl groups (C_8-C_{18}) are derived from coconut oil, as surfactants in emulsifier blends at levels not in excess of 5 percent by weight of emulsifier blends that are added to herbicides for application to corn or sorghum.

Diethanolamide condensate based on a mixture of saturated and unsaturated soybean oil fatty acids (C_{16}-C_{18}) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

Diethanolamide condensate based on stripped coconut fatty acids ($C_{10}C_{18}$) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

a-(*p*-Dodecylphenyl)-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a proplyene tetramer isomer) with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70.

Ethylene dichloride.

Polyglyceryl phthalate ester of coconut oil fatty acids.

a-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70.

a-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with 1 mole of ethylene oxide.

Sodium acrylate and acrylamide copolymer with a minimum average molecular weight of 10,000,000 in which 30 percent of the polymer is comprised of acrylate units and 70 percent acrylamide units, for use as a drift control agent in herbicide formulations applied to crops at a level not to exceed 0.5 ounces of the additive per acre.

§ 172.712 Dimethyl dialkyl ammonium chloride.

Dimethyl dialkyl ammonium chloride may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by ammonolysis of natural tallow fatty acids to form amines that are subsequently reacted with methyl chloride to form the quaternary ammonium compounds consisting primarily of dimethyl dioctadecyl ammonium chloride and dimethyl dihexadecyl ammonium chloride. The additive may contain residues of isopropyl alcohol not in excess of 18 percent by weight when used as a processing solvent.

(b) The food additive contains not more than a total of 2 percent by weight of free amine and amine hydrochloride.

(c) The food additive is used as a decolorizing agent in the clarification of refinery sugar liquors. It is added only at the defecation/clarification stage of sugar liquor refining in an amount not to exceed 700 parts per million by weight of sugar solids.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

§ 172.715 Calcium lignosulfonate.

Calcium lignosulfonate may be safely used in or on food, subject to the provisions of this section.

(a) Calcium lignosulfonate consists of sulfonated lignin, primarily as calcium and sodium salts.

(b) It is used in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect when added as a dispersing agent and stabilizer in pesticides for preharvest or postharvest application to bananas.

§ 172.720 Calcium lactobionate.

The food additive calcium lactobionate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the calcium salt of lactobionic acid (4-(β, D-galactosido)-D-gluconic acid) produced by the oxidation of lactose.

(b) It is used or intended for use as a firming agent in dry pudding mixes at a level not greater than that required to accomplish the intended effect.

§ 172.725 Gibberellic acid and its potassium salt.

The food additives gibberellic acid and its potassium salt may be used in the malting of barley in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) The gibberellic acid is produced by deep-culture fermentation of a suitable nutrient medium by a strain of Fusarium moniliforme or a selection of this culture.

(2) The gibberellic acid produced is of 80 percent purity or better.

(3) The empirical formula of gibberellic acid is represented by $C_{19}H_{22}O_6$.

(4) Potassium gibberellate is the potassium salt of the specified gibberellic acid.

(5) The potassium gibberellate is of 80 percent purity or better.

(6) The gibberellic acid or potassium gibberellate may be diluted with substances generally recognized as safe in foods or with salts of fatty acids conforming to § 172.863.

(b) They are used or intended for use in the malting of barley under conditions whereby the amount of either or both additives present in the malt is not in excess of 2 parts per million expressed as gibberellic acid, and the treated malt is to be used in the production of fermented malt beverages or distilled spirits only, whereby the finished distilled spirits contain none and the finished malt beverage contains not more than 0.5 part per million of gibberellic acid.

(c) To insure the safe use of the food additives the label of the package shall bear, in addition to the other information required by the Act:

(1) The name of the additive, "gibberellic acid" or "potassium gibberellate", whichever is appropriate.

(2) An accurate statement of the concentration of the additive contained in the package.

(3) Adequate use directions to provide not more than 2 parts per million of gibberellic acid in the finished malt.

(4) Adequate labeling directions to provide that the final malt is properly labeled as described in paragraph (d) of this section.

(d) To insure the safe use of the additive the label of the treated malt shall bear, in addition to the other information required by the Act, the statements:

(1) "Contains not more than 2 parts per million ————————", the blank being filled in with the words "gibberellic acid" or "potassium gibberellate", whichever is appropriate; and

(2) "Brewer's malt—To be used in the production of fermented malt beverages only" or "Distiller's malt—To be used in the production of distilled spirits only", whichever is appropriate.

§ 172.730 Potassium bromate.

The food additive potassium bromate may be safely used in the malting of barley under the following prescribed conditions:

(a)(1) It is used or intended for use in the malting of barley under conditions whereby the amount of the additive present in the malt from the treatment does not exceed 75 parts per million of bromate (calculated as Br), and the treated malt is used only in the production of fermented malt beverages or distilled spirits.

(2) The total residue of inorganic bromides in fermented malt beverages, resulting from the use of the treated malt plus additional residues of inorganic bromides that may be present from uses in accordance with other regulations in this chapter promulgated under sections 408 and/or 409 of the act, does not exceed 25 parts per million of bromide (calculated as Br). No tolerance is established for bromide in distilled spirits because there is evidence that inorganic bromides do not pass over in the distillation process.

(b) To assure safe use of the additive, the label or labeling of the food additive shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive.

(2) Adequate directions for use.

(c) To assure safe use of the additive, the label or labeling of the treated malt shall bear, in addition to other information required by the Act, the statement, "Brewer's Malt—To be used in the production of fermented malt beverages only", or "Distiller's Malt—To be used in the production of distilled spirits only", whichever is the case.

§ 172.735 Glycerol ester of wood rosin.

Glycerol ester of wood rosin may be safely used in food in accordance with the following prescribed conditions:

(a) It has an acid number of 3 to 9, a drop-softening point of 88° C-96° C; and a color of N or paler as determined in accordance with Official Naval Stores Standards of the United States. It is purified by countercurrent steam distillation.

(b) It is used to adjust the density of citrus oils used in the preparation of beverages whereby the amount of the additive does not exceed 100 parts per million of the finished beverage.

§ 172.755 Stearyl monoglyceridyl citrate.

The food additive stearyl monoglyceridyl citrate may be safely used in food in accordance with the following provisions:

(a) The additive is prepared by controlled chemical reaction of the following:

Reactant	Limitations
Citric acid	
Monoglycerides of fatty acids.	Prepared by the glycerolysis of edible fats and oils or derived from fatty acids conforming with § 172.860.
Stearyl alcohol	Derived from fatty acids conforming with § 172.860, or derived synthetically in conformity with § 172.864

(b) The additive stearyl monoglyceridyl citrate, produced as described under paragraph (a) of this section, meets the following specifications:

Acid number 40 to 52.
Total citric acid 15 to 18 percent.
Saponification number 215-255.

(c) The additive is used or intended for use as an emulsion stabilizer in or with shortenings containing emulsifiers.

§ 172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).

The food additive succistearin (stearoyl propylene glycol hydrogen succinate) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the reaction product of succinic anhydride, fully hydrogenated vegetable oil (predominantly C_{16} or C_{18} fatty acid chain length), and propylene glycol.

(b) The additive meets the following specifications:

Acid number 50-150.
Hydroxyl number 15-50.
Succinated ester content 45-75 percent.

(c) The additive is used or intended for use as an emulsifier in or with shortenings and edible oils intended for use in cakes, cake mixes, fillings, icings, pastries, and toppings, in accordance with good manufacturing practice.

§ 172.770 Ethylene oxide polymer.

The polymer of ethylene oxide may be safely used as a foam stabilizer in fermented malt beverages in accordance with the following conditions.

(a) It is the polymer of ethylene oxide having a minimum viscosity of 1,500 centipoises in a 1 percent aqueous solution at 25° C.

(b) It is used at a level not to exceed 300 parts per million by weight of the fermented malt beverage.

(c) The label of the additive bears directions for use to insure compliance with paragraph (b) of this section.

§ 172.775 Methacrylic acid-divinylbenzene copolymer.

Methacrylic acid-divinylbenzene copolymer may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of methacrylic acid and divinylbenzene. The divinylbenzene functions as a cross-linking agent and constitutes a minimum of 4 percent of the polymer.

(b) Aqueous extractives from the additive do not exceed 2 percent (dry basis) after 24 hours at 25° C.

(c) The additive is used as a carrier of vitamin B_{12} in foods for special dietary use.

Subpart I—Multipurpose Additives

§ 172.802 Acetone peroxides.

The food additive acetone peroxides may be safely used in flour, and in bread and rolls where standards of identity do not preclude its use, in accordance with the following prescribed conditions:

(a) The additive is a mixture of monomeric and linear dimeric acetone peroxide, with minor proportions of higher polymers, manufactured by reaction of hydrogen peroxide and acetone.

(b) The additive may be mixed with an edible carrier to give a concentration of: (1) 3 grams to 10 grams of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in flour maturing and bleaching; or (2) approximately 0.75 gram of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in dough conditioning.

(c) It is used or intended for use: (1) In maturing and bleaching of flour in a quantity not more than sufficient for such effect; and (2) as a dough-conditioning agent in bread and roll production at not to exceed the quantity of hydrogen peroxide equivalent necessary for the artificial maturing effect.

(d) To insure safe use of the additive, the label of the food additive container and any intermediate premix thereof shall bear, in addition to the other information required by the act:

(1) The name of the additive, "acetone peroxides".

(2) The concentration of the additive expressed in hydrogen peroxide equivalents per 100 grams.

(3) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.804 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent or for an authorized technological purpose in foods for which standards of identity established under section 401 of the Act do not preclude such use under the following conditions:

(a) Aspartame is the chemical

1-methyl *N*-L-α-aspartyl-L-phenylalanine ($C_{14}H_{18}N_2O_5$).

(b) The additive meets the following specifications:

(1) Not less than 98.0 percent and not more than the equivalent of 102.0 percent $C_{14}H_{18}N_2O_5$ (aspartame), calculated on the dried basis (4 hours at 105° C), as determined by the following analytical method.

APPARATUS

Titration vessel. Glass beaker or flask, 150 milliliters.

Buret. 50 milliliters with 0.1-milliliter gradations, equipped with tetrafluoroethylene polymer stopcock.

Aluminum foil.

Optional equipment. Magnetic stirrer and tetrafluoroethylene polymer-coated magnetic bar.

REAGENTS

Lithium metal.

Methyl alcohol. Absolute, A.C.S. reagent grade.

Benzene. Anhydrous, A.C.S. reagent grade.

Thymol blue (thymolsulfonephthalein). A.C.S. reagent grade.

Ethyl alcohol. 95 percent.

Benzoic acid. A.C.S. reagent grade, of specified purity dried at 80° C.

N,N-Dimethylformamide. A.C.S. reagent grade.

Lithium methoxide solution. 0.1 normal; dissolve 600 milligrams of lithium metal in 150 milliliters of absolute methyl alcohol and 850 milliliters of benzene. Filter the solution if cloudy.

Thymol blue solution. Dissolve 100 milligrams of thymol blue in 100 milliliters of 95 percent ethyl alcohol. Filter if necessary.

PROCEDURE

General instructions. Perform in triplicate both the standardization of the lithium methoxide solution and the titration of the sample. Perform one titration of the solvent blank, i.e., *N,N*-dimethylformamide. Cover the titration vessel with aluminum foil while dissolving the samples and throughout the titration to decrease carbon dioxide absorption.

Titration of solvent blank. Add 35 milliliters of *N,N*-dimethylformamide to the titration vessel. Add 5 drops of the thymol blue solution and titrate the mixture with lithium methoxide solution to an end point indicated by a color change from yellow to blue.

Determination of normality of the lithium methoxide solution. Place a weighed sample of benzoic acid (approximately 80 milligrams) in the titration vessel, and 35 milliliters of *N,N*-dimethylformamide and dissolve the sample. Add 5 drops of thymol blue solution to the dissolved sample and titrate with the lithium methoxide solution to an end point indicated by a color change from yellow to blue.

Titration of the aspartame sample. Place a weighed sample of aspartame (approximately 150 milligrams dried at 105° C for 4 hours and stored in a desiccator) in the titration vessel, add 35 milliliters of *N,N*-dimethylformamide and dissolve the sample. Add 5 drops of thymol blue solution to the dissolved sample and titrate with the lithium methoxide solution to an end point indicated by a color change from yellow to blue.

CALCULATIONS

$$N = \frac{J}{122.12(S-B)}$$

Percent aspartame in sample =

$$\frac{(294.3)(A-B)(N)}{K \times 100}$$

Where:

N = Accurate normality of the lithium methoxide solution.

S = Milliliters of lithium methoxide solution required to titrate the benzoic acid.

A = Milliliters of lithium methoxide solution required to titrate the aspartame sample.

B = Milliliters of lithium methoxide solution required to titrate the solvent blank.

J = Milligrams of benzoic acid standard.

K = Milligrams of aspartame sample.

(2) Specific rotation,

$$[\alpha]^{20}_{D}$$

shall be between +12.5° and +17.5°, calculated on the dried basis (4 hours at 105° C) in accordance with the test for optical rotation described in the "Food Chemicals Codex," 2d Ed. (1972), page 939, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Weigh accurately about 4 grams of sample and dissolve it in sufficient 15*N* formic acid to make exactly 100 milliliters of solution, and complete the determination of the rotation in a 100-millimeter tube within 30 minutes after preparing the solution.[11]

(3) 5-Benzyl-3,6-dioxo-2-piperazineacetic acid (diketopiperazine) not to exceed 2.0 percent as determined by the following analytical method:

APPARATUS

Gas chromatograph. With hydrogen flame ionization detector and designed for handling glass columns with on-column injection (Micro-Tek 220 or equivalent). Chromatograph conditions should be optimized to obtain maximum resolution for the specific instrument used. To preclude buildup of silico oxide, clean the detector with acetone frequently. Approximate operating conditions are:

Column temperature: 200° C.

Detector temperature: 275° C.

Inlet temperature: 200° C.

Carrier gas (helium) flow rate: 75 milliliters per minute.

Hydrogen and air flow to burner: Optimize to give maximum sensitivity.

Sample size: 3 microliters.

Elution time: 7-9 minutes.

Recorder: 1 millivolt full scale (for the Micro-Tek 220, the attenuation is 16×10).

Chromatograph column: 6 feet × 4 millimeters I.D. glass column packed with OV-1 on 80-100 mesh Supelcoport (Supelco, Inc., or equivalent). Condition the column overnight at 250° C before readjustment and equilibration to the operation conditions.

Oven. Capable of maintaining 80±1° C for 30 minutes.

Glass manifold. Suitable for evaporating samples to dryness over steam bath; the apparatus may have an optional gas flow over the sample to enhance the rate of solvent evaporation.

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[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW, Washington, D.C. 20037.

Vials. 2-dram size with tetrafluoroethylene polymer-lined cap.

REAGENTS

N,N-Dimethylformamide. A.C.S. reagent grade.

N, O-Bis (trimethylsilyl) acetamide.

Silylation reagent. Dilute by volume three parts *N,O*-bis (trimethylsilyl) acetamide with two parts *N,N*-dimethylformamide. Prepare fresh before use.

Methyl alcohol. Anyhydrous, A.C.S. reagent grade.

5-Benzyl-3,6-dioxo-2-piperazineacetic acid. Specifications: Purity, not less than 99 percent; minimum melting point, 243° C; specific rotation of a 1 percent solution (in acetic acid), between −9° and −11°; total impurities determined by thin layer chromatography, less than 0.5 percent; impurities determined by gas chromatography, less than 1 percent for any single impurity. A sample of the reagent and test procedures for verification of specifications may be obtained from Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave., NW., Washington, DC 20037.

PROCEDURE

Preparation of the standard. Place a weighed sample of 5-benzyl-3,6-dioxo-2-piperazineacetic acid (25 milligrams) into a 50-milliliter volumetric flask. Add methyl alcohol to dissolve the solid standard and dilute to volume. Dilute a 10-milliliter portion of the above solution to 50 milliliters with methyl alcohol in another 50-milliliter volumetric flask. The concentration of this standard solution is 0.1 milligram per milliliter. Pipet 2 milliliters of the standard solution into a 2-dram vial and evaporate the solvent to dryness. Add 1 milliliter of the silylation reagent to the dried sample, cap the vial tightly, shake and place in an 80° C oven for 30 minutes. Remove from oven, shake vial 15 seconds and cool to room temperature. Inject 3 microliters of this solution into the gas chromatograph and measure the peak height. The standard should be injected either immediately before or after each sample for proper quantification.

Preparation of the aspartame sample. Place a weighed sample of aspartame (approximately 10 milligrams) into a 2-dram vial. Add 1 milliliter of silylation reagent to the vial, cap tightly, shake and place in an 80° C oven for 30 minutes. Remove from oven, shake vial 15 seconds and cool to room temperature. Inject 3 microliters of this solution into the gas chromatograph and measure the subject compound peak height.

CALCULATION

Milligrams of 5-benzyl-3,6-dioxo-2-piperazineacetic acid in aspartame =

$$\frac{\text{Peak height of aspartame sample}}{\text{Peak height of standard sample}} \times 0.2$$

Percent 5-benzyl-3,6-dioxo-2-piperazineacetic acid in aspartame =

$$\frac{\text{Milligrams of subject compound in aspartame}}{\text{Milligrams of aspartame sample}} \times 100$$

(c) The additive may be used as a sweetener in the following foods:

(1) Dry, free-flowing sugar substitutes for table use (not to include use in cooking) in package units not to exceed the sweetening equivalent of 2 teaspoonfuls of sugar.

(2) Sugar substitute tablets for sweetening hot beverages, including coffee and tea. L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(3) Cold breakfasts cereals.

(4) Chewing gum.

(5) Dry bases for:

(i) Beverages.

(ii) Instant coffee.

(iii) Gelatins, puddings, and fillings.

(iv) Dairy product analog toppings.

(6) Carbonated beverages and carbonated beverage syrup bases.

(7) Chewable multivitamin food supplements.

(8) Noncarbonated, refrigerated single-strength and frozen concentrates of the following beverages:

(i) Fruit juice based drinks (where food standards do not preclude such use).

(ii) Fruit flavored drinks and ades.

(iii) Imitation fruit flavored drinks and ades.

(9) Frozen stick-type confections and novelties.

(10) Breath mints.

(11) Tea beverages to include ready-to-serve, liquid concentrates, and dry bases.

(d) The additive may be used as a flavor enhancer in chewing gum.

(e) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The principal display panel of any intermediate mix of the additive for manufacturing purposes shall bear

a statement of the concentration of the additive contained therein;

(2) The label of any food containing the additive shall bear, either on the principal display panel or on the information panel, the following statement:

PHENYLKETONURICS: CONTAINS PHENYLALANINE

The statement shall appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) When the additive is used in a sugar substitute for table use, its label shall bear instructions not to use in cooking or baking.

(f) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with Part 105 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 48 FR 31382, July 8, 1983; 49 FR 22468, May 30, 1984; 51 FR 43000-43002, Nov. 28, 1986]

§ 172.806 Azodicarbonamide.

The food additive azodicarbonamide may be safely used in food in accordance with the following prescribed conditions:

(a) It is used or intended for use:

(1) As an aging and bleaching ingredient in cereal flour in an amount not to exceed 2.05 grams per 100 pounds of flour (0.0045 percent; 45 parts per million).

(2) As a dough conditioner in bread baking in a total amount not to exceed 0.0045 percent (45 parts per million) by weight of the flour used, including any quantity of azodicarbonamide added to flour in accordance with paragraph (a)(1) of this section.

(b) To assure safe use of the additive:

(1) The label and labeling of the additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the Act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or the strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions for use.

§ 172.808 Copolymer condensates of ethylene oxide and propylene oxide.

Copolymer condensates of ethylene oxide and propylene oxide may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1) α-Hydro-*omega*-hydroxy-poly (oxyethylene) poly(oxypropylene)-(55-61 moles)poly(oxyethylene) block copolymer, having a molecular weight range of 9,760-13,200 and a cloud point above 100° C in 1 percent aqueous solution.

(2) α-Hydro-*omega*-hydroxy-poly (oxyethylene)poly(oxypropylene)-(53-59 moles)poly(oxyethylene)(14-16 moles) block copolymer, having a molecular weight range of 3,500-4,125 and a cloud point of 9° C-12° C in 10 percent aqueous solution.

(3) α-Hydro-*omega*-hydroxy-poly(oxyethylene)/poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer, having a minimum average molecular weight of 1900 and a minimum cloud point of 9° C-12° C in 10 percent aqueous solution.

(4) α-Hydro-*omega*-hydroxy-poly(oxyethylene) poly (oxypropylene)-(51-57 moles) poly(oxyethylene) block copolymer, having an average molecular weight of 14,000 and a cloud point above 100° C in 1 percent aqueous solution.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used in practice as a solubilizing and stabilizing agent in flavor concentrates (containing authorized flavoring oils) for use in foods for which standards of identity established under section 401 of the act do not preclude such use, provided that the weight of the additive does not exceed the weight of the flavoring oils in the flavor concentrate.

(2) The additive identified in paragraph (a)(2) of this section is used as a processing aid and wetting agent in combination with dioctyl sodium sulfosuccinate for fumaric acid as prescribed in § 172.810.

(3) The additive identified in paragraph (a)(3) of this section is used:

(i) As a surfactant and defoaming agent, at levels not to exceed 0.05 percent by weight, in scald baths for poultry defeathering, followed by potable water rinse. The temperatures of the scald baths shall be not less than 125° F.

(ii) As a foam control and rinse adjuvant in hog dehairing machines at a use level of not more than 5 grams per hog.

(4) The additive identified in paragraph (a)(4) of this section is used as a dough conditioner in yeast-leavened bakery products for which standards of identity established under section 401 of the Act do not preclude such use, provided that the amount of the additive dose not exceed 0.5 percent by weight of the flour used.

[42 FR 14491, Mar. 15, 1977, as amended at 46 FR 57476, Nov. 24, 1981]

§ 172.810 Dioctyl sodium sulfosuccinate.

The food additive dioctyl sodium sulfosuccinate, which meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 102-104, which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), may be safely used in food in accordance with the following prescribed conditions:

(a) As a wetting agent in the following fumaric acid-acidulated foods: Dry gelatin dessert, dry beverage base, and fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry gelatin dessert and dry beverage base shall bear adequate directions for use, and the additive shall be used in such an amount that the finished gelatin dessert will contain not in excess of 15 parts per million of the additive and the finished beverage or fruit juice drink will contain not in excess of 10 parts per million of the additive.

(b) As a processing aid in sugar factories in the production of unrefined cane sugar, in an amount not in excess of 0.5 part per million of the additive per percentage point of sucrose in the juice, syrup, or massecuite being processed, and so used that the final molasses will contain no more than 25 parts per million of the additive.

(c) As a solubilizing agent on gums and hydrophilic colloids to be used in food as stabilizing and thickening agents, when standards of identity do not preclude such use. The additive is used in an amount not to exceed 0.5 percent by weight of the gums or hydrophilic colloids.

(d) As an emulsifying agent for cocoa fat in noncarbonated beverages containing cocoa, whereby the amount of the additive does not exceed 25 parts per million of the finished beverage.

(e) As a dispersing agent in "cocoa with dioctyl sodium sulfosuccinate for manufacturing" that conforms to the provisions of § 163.117 of this chapter and the use limitations prescribed in § 172.520, in an amount not to exceed 0.4 percent by weight thereof.

(f) As a processing aid and wetting agent in combination with α-hydro-*omega* - hydroxy - poly(oxyethylene) - poly-(oxypropylene) (53-59 moles) poly(oxyethylene) (14-16 moles) block copolymer, having a molecular weight range of 3,500-4,125 and a cloud point of 9° C-12° C in 10 percent aqueous solution, for fumaric acid used in fumaric acid-acidulated dry beverage base and in fumaric acid-acidulated fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry beverage base shall bear adequate directions for use, and the additives shall be used in such an amount that the finished beverage or fruit juice drink will contain not in excess of a total of 10 parts per million of the dioctyl sodium sulfosuccinate-block copolymer combination.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.812 Glycine.

The food additive glycine may be safely used for technological purposes in food in accordance with the following prescribed conditions:

(a) The additive complies with the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 140, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) The additive is used or intended for use as follows:

Uses	Limitations
As a masking agent for the bitter aftertaste of saccharin used in manufactured beverages and beverage bases.	Not to exceed 0.2 percent in the finished beverage.
As a stabilizer in mono- and diglycerides prepared by the glycerolysis of edible fats or oils.	Not to exceed 0.02 percent of the mono- and diglycerides.

(c) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The labeling of the additive shall bear adequate directions for use of the additive in compliance with the provisions of this section.

(2) The labeling of beverage bases containing the additive shall bear adequate directions for use to provide that beverages prepared therefrom shall contain no more than 0.2 percent glycine.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.814 Hydroxylated lecithin.

The food additive hydroxylated lecithin may be safely used as an emulsifier in foods in accordance with the following conditions:

(a) The additive is obtained by the treatment of lecithin in one of the following ways, under controlled conditions whereby the separated fatty acid fraction of the resultant product has an acetyl value of 30 to 38:

(1) With hydrogen peroxide, benzoyl peroxide, lactic acid, and sodium hydroxide.

(2) With hydrogen peroxide, acetic acid, and sodium hydroxide.

(b) It is used or intended for use, in accordance with good manufacturing practice, as an emulsifier in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, "hydroxylated lecithin".

(2) Adequate directions for its use.

§ 172.816 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in food in accordance with the following conditions:

(a) It is the methyl glucoside-coconut oil ester having the following specifications:

Acid number	10-20
Hydroxyl number	200-300
pH (5% aqueous)	4.8-5.0
Saponification number	178-190

(b) It is used or intended for use as follows:

(1) As an aid in crystallization of sucrose and dextrose at a level not to exceed the minimum quantity required to produce its intended effect.

(2) As a surfactant in molasses at a level not to exceed 320 parts per million in the molasses.

§ 172.818 Oxystearin.

The food additive oxystearin may be safely used in foods, when such use is not precluded by standards of identity in accordance with the following conditions:

(a) The additive is a mixture of the glycerides of partially oxidized stearic and other fatty acids obtained by heating hydrogenated cottonseed or soybean oil under controlled conditions, in the presence of air and a suitable catalyst which is not a food additive as so defined. The resultant product meets the following specifications:

Acid number	Maximum 15.
Iodine number	Maximum 15.
Saponification number	225–240.
Hydroxyl number	30–45.
Unsaponifiable material	Maximum 0.8 percent.
Refractive index (butyro)	60 ± 1 at 48° C.

(b) It is used or intended for use as a crystallization inhibitor in vegetable oils and as a release agent in vegetable oils and vegetable shortenings, whereby the additive does not exceed 0.125 percent of the combined weight of the oil or shortening.

(c) To insure safe use of the additive, the label and labeling of the additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide an oil or shortening that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.820 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a) *Identity.* (1) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(2) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols when tested by the analytical methods prescribed in paragraph (b) of this section.

(b) *Analytical method.* (1) The analytical method prescribed in the National Formulary XV (1980), page 1244, for polyethylene glycol 400 shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights of 450 or higher.

(2) The following analytical method shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights below 450.

ANALYTICAL METHOD

ETHYLENE GLYCOL AND DIETHYLENE GLYCOL CONTENT OF POLYETHYLENE GLYCOLS

The analytical method for determining ethylene glycol and diethylene glycol is as follows:

APPARATUS

Gas chromatograph with hydrogen flame ionization detector (Varian Aerograph 600 D or equivalent). The following conditions shall be employed with the Varian Aerograph 600 D gas chromatograph:

Column temperature: 165° C.

Inlet temperature: 260° C.

Carrier gas (nitrogen) flow rate: 70 milliliters per minute.

Hydrogen and air flow to burner: Optimize to give maximum sensitivity.

Sample size: 2 microliters.

Elution time: Ethylene glycol: 2.0 minutes. Diethylene glycol: 6.5 minutes.

Recorder: −0.5 to +1.05 millivolt, full span, 1 second full response time.

Syringe: 10-microliter (Hamilton 710 N or equivalent).

Chromatograph column: 5 feet × ⅛ inch. I.D. stainless steel tube packed with sorbitol (Mathieson-Coleman-Bell 2768 Sorbitol SX850, or equivalent) 12 percent in H_2O by weight on 60–80 mesh nonacid washed diatomaceous earth (Chromosorb W. Johns-Manville, or equivalent).

REAGENTS AND MATERIALS

Carrier gas, nitrogen: Commercial grade in cylinder equipped with reducing regulator to provide 50 p.s.i.g. to the gas chromatograph.

Ethylene glycol: Commercial grade. Purify if necessary, by distillation.

Diethylene glycol: Commercial grade. Purify, if necessary, by distillation.

Glycol standards: Prepare chromatographic standards by dissolving known amounts of ethylene glycol and diethylene glycol in water. Suitable concentrations for standardization range from 1 to 6 milligrams of each component per milliliter (for example 10 milligrams diluted to volume in a 10-milliliter volumetric flask is equivalent to 1 milligram per milliliter).

STANDARDIZATION

Inject a 2-microliter aliquot of the glycol standard into the gas chromatograph employing the conditions described above. Measure the net peak heights for the ethylene glycol and for the diethylene glycol. Record the values as follows:

A = Peak height in millimeters of the ethylene glycol peak.

B = milligrams of ethylene glycol per milliliter of standard solution.

C=Peak height in millimeters of the diethylene glycol peak.

D=Milligrams of diethylene glycol per milliliter of standard solution.

PROCEDURE

Weigh approximately 4 grams of polyethylene glycol sample accurately into a 10-milliliter volumetric flask. Dilute to volume with water. Mix the solution thoroughly and inject a 2-microliter aliquot into the gas chromatograph. Measure the heights, in millimeters, of the ethylene glycol peak and of the diethylene glycol peak and record as E and F, respectively.

$$\text{Percent ethylene glycol} = (E \times B)/(A \times \text{sample weight in grams})$$

$$\text{Percent diethylene glycol} = (F \times D)/(C \times \text{sample weight in grams})$$

(c) *Uses.* It may be used, except in milk or preparations intended for addition to milk, as follows:

(1) As a coating, binder, plasticizing agent, and/or lubricant in tablets used for food.

(2) As an adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners identified in § 180.37 of this chapter.

(3) As an adjuvant in dispersing vitamin and/or mineral preparations.

(4) As a coating on sodium nitrite to inhibit hygroscopic properties.

(d) *Limitations.* (1) It is used in an amount not greater than that required to produce the intended physical or technical effect.

(2) A tolerance of zero is established for residues of polyethylene glycol in milk.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.822 Sodium lauryl sulfate.

The food additive sodium lauryl sulfate may be safely used in food in accordance with the following conditions:

(a) The additive meets the following specifications:

(1) It is a mixture of sodium alkyl sulfates consisting chiefly of sodium lauryl sulfate [$CH_3(CH_2)_{10}CH_2OSO_3Na$].

(2) It has a minimum content of 90 percent sodium alkyl sulfates.

(b) It is used or intended for use:

(1) As an emulsifier in or with egg whites whereby the additive does not exceed the following limits:

Egg white solids, 1,000 parts per million.
Frozen egg whites, 125 parts per million.
Liquid egg whites, 125 parts per million.

(2) As a whipping agent at a level not to exceed 0.5 percent by weight of gelatine used in the preparation of marshmallows.

(3) As a surfactant in:

(i) Fumaric acid-acidulated dry beverage base whereby the additive does not exceed 25 parts per million of the finished beverage and such beverage base is not for use in a food for which a standard of identity established under section 401 of the Act precludes such use.

(ii) Fumaric acid-acidulated fruit juice drinks whereby the additive does not exceed 25 parts per million of the finished fruit juice drink and it is not used in a fruit juice drink for which a standard of identity established under section 401 of the Act precludes such use.

(4) As a wetting agent at a level not to exceed 10 parts per million in the partition of high and low melting fractions of crude vegetable oils and animal fats, provided that the partition step is followed by a conventional refining process that includes alkali neutralization and deodorization of the fats and oils.

(c) To insure the safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, sodium lauryl sulfate.

(2) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 18668, May 2, 1978]

§ 172.824 Sodium mono- and dimethyl naphthalene sulfonates.

The food additive sodium mono- and dimethyl naphthalene sulfonates may be safely used in accordance with the following prescribed conditions:

(a) The additive has a molecular weight range of 245-260.

(b) The additive is used or intended for use:

(1) In the crystallization of sodium carbonate in an amount not to exceed 250 parts per million of the sodium carbonate. Such sodium carbonate is used or intended for use in potable water systems to reduce hardness and aid in sedimentation and coagulation by raising the pH for the efficient utilization of other coagulation materials.

(2) As an anticaking agent in sodium nitrite at a level not in excess of 0.1 percent by weight thereof for authorized uses in cured fish and meat.

(3) In the washing or to assist in the lye peeling of fruits and vegetables as prescribed in § 173.315 of this chapter.

(c) In addition to the general labeling requirements of the Act:

(1) Sodium carbonate produced in accordance with paragraph (b)(1) of this section shall be labeled to show the presence of the additive and its label or labeling shall bear adequate directions for use.

(2) Sodium nitrite produced in accordance with paragraph (b)(2) of this section shall bear the labeling required by § 172.175 and a statement declaring the presence of sodium mono- and dimethyl naphthalene sulfonates.

§ 172.826 Sodium stearyl fumarate.

Sodium stearyl fumarate may be safely used in food in accordance with the following conditions:

(a) It contains not less than 99 percent sodium stearyl fumarate calculated on the anhydrous basis, and not more than 0.25 percent sodium stearyl maleate.

(b) The additive is used or intended for use:

(1) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(2) As a conditioning agent in dehydrated potatoes in an amount not to exceed 1 percent by weight thereof.

(3) As a stabilizing agent in non-yeast-leavened bakery products in an amount not to exceed 1 percent by weight of the flour used.

(4) As a conditioning agent in processed cereals for cooking in an amount not to exceed 1 percent by weight of the dry cereal, except for foods for which standards of identity preclude such use.

(5) As a conditioning agent in starch-thickened or flour-thickened foods in an amount not to exceed 0.2 percent by weight of the food.

§ 172.828 Acetylated monoglycerides.

The food additive acetylated monoglycerides may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive is manufactured by:

(1) The interesterification of edible fats with triacetin and in the presence of catalytic agents that are not food additives or are authorized by regulation, followed by a molecular distillation or by steam stripping; or

(2) The direct acetylation of edible monoglycerides with acetic anhydride without the use of catalyst or molecular distillation, and with the removal by vacuum distillation, if necessary, of the acetic acid, acetic anhydride, and triacetin.

(b) The food additive has a Reichert-Meissl value of 75-200 and an acid value of less than 6.

(c) The food additive is used at a level not in excess of the amount reasonably required to produce its intended effect in food, or in food-processing, food-packing, or food-storage equipment.

[42 FR 14491, Mar. 15, 1977, as amended at 50 FR 3508, Jan. 25, 1985]

§ 172.830 Succinylated monoglycerides.

The food additive succinylated monoglycerides may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of semi- and neutral succinic acid esters of mono- and diglycerides produced by the succinylation of a product obtained by the glycerolysis of edible fats and oils, or by the direct esterification of glycerol with edible fat-forming fatty acids.

(b) The additive meets the following specifications:

Succinic acid content	14.8%-25.6%
Melting point	50 C-60 C.
Acid number	70-120

(c) The additive is used or intended for use in the following foods:

(1) As an emulsifier in liquid and plastic shortenings at a level not to exceed 3 percent by weight of the shortening.

(2) As a dough conditioner in bread baking, when such use is permitted by an appropriate food standard, at a level not to exceed 0.5 percent by weight of the flour used.

§ 172.832 Monoglyceride citrate.

A food additive that is a mixture of glyceryl monooleate and its citric acid monoester manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions may be safely used as a synergist and solubilizer for antioxidants in oils and fats, when used in accordance with the conditions prescribed in this section.

(a) The food additive meets the following specifications:

Acid number, 70-100.
Total citric acid (free and combined), 14 percent-17 percent.

(b) It is used, or intended for use, in antioxidant formulations for addition to oils and fats whereby the additive does not exceed 200 parts per million of the combined weight of the oil or fat and the additive.

(c) To assure safe use of the additive:

(1) The container label shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or accompanying labeling shall bear adequate directions for the use of the additive which, if followed, will result in a food that complies with the requirements of this section.

§ 172.834 Ethoxylated mono- and diglycerides.

The food additive ethoxylated mono-and diglycerides (polyoxyethylene (20) mono- and diglycerides of fatty acids) (polyglycerate 60) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by:

(1) Glycerolysis of edible fats primarily composed of stearic, palmitic, and myristic acids; or

(2) Direct esterification of glycerol with a mixture of primarily stearic, palmitic, and myristic acids;

to yield a product with less than 0.3 acid number and less than 0.2 percent water, which is then reacted with ethylene oxide.

(b) The additive meets the following specifications:

Saponification number, 65-75.
Acid number, 0-2.
Hydroxyl number, 65-80.
Oxyethylene content, 60.5-65.0 percent.

(c) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
1. As an emulsifier in pan-release agents for and as a dough conditioner in yeast-leavened bakery products	Not to exceed levels required to produce the intended effects, total not to exceed 0.5 percent by weight of the flour used.
2. As an emulsifier in cakes and cake mixes	Not to exceed 0.5 percent by weight of the dry ingredients.
3. As an emulsifier in whipped vegetable oil toppings and topping mixes	Not to exceed 0.45 percent by weight of the finished whipped vegetable oil toppings.
4. As an emulsifier in icings and icing mixes	Not to exceed 0.5 percent by weight of the finished icings.
5. As an emulsifier in frozen desserts	Not to exceed 0.2 percent by weight of the finished frozen desserts.
6. As an emulsifier in edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee	Not to exceed 0.4 percent by weight of the finished vegetable fat-water emulsions.

(d) When the name "polyglycerate 60" is used in labeling it shall be followed by either "polyoxyethylene (20) mono-and diglycerides of fatty acids" or "ethoxylated mono- and diglycerides" in parentheses.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 37973, July 26, 1977; 50 FR 49536, Dec. 3, 1985]

§ 172.836 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45-55.
Acid number 0-2.
Hydroxyl number 81-96.
Oxyethylene content 65 percent-69.5 percent.

(c) It is used or intended for use as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;
(ii) Polysorbate 65;
(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with sorbitan monostearate may be used in excess of 0.4 percent, provided that the amount of the additive does not exceed 0.77 percent and the amount of sorbitan monostearate does not exceed 0.27 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.
(ii) Sorbitan monostearate.

When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.61 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with sorbitan monostearate, in nonstandardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 0.5 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with sorbitan monostearate in any combination of up to 0.5 percent of polysorbate 60 and up to 1 percent of sorbitan monostearate: *Provided*, That the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) [Reserved]

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.
(ii) Sorbitan monostearate.

When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the weight of the cake icings and cake fillings. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.7 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(6) To impart greater opacity to sugar-type confection coatings whereby the maximum amount of the additive does not exceed 0.2 percent of the weight of the finished sugar coating.

(7) As an emulsifier in nonstandardized dressings whereby the maximum amount of the additive does not exceed 0.3 percent of the weight of the finished dressings.

(8) As an emulsifier, alone or in combination with polysorbate 80, in shortenings and edible oils intended for

use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 80 in any combination providing no more than 1 percent of polysorbate 60 and no more than 1 percent of polysorbate 80, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1-percent limitation specified in paragraph (c)(8) (i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Sorbitan monostearate.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(10) As a foaming agent in nonalcoholic mixes, to be added to alcoholic beverages in the preparation of mixed alcoholic drinks, at a level not to exceed 4.5 percent by weight of the nonalcoholic mix.

(11) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(12) As an emulsifier, alone or in combination with sorbitan monostearate, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with § 172.878 and/or petroleum wax conforming with § 172.886 for use as protective coatings on raw fruits and vegetables.

(13) As a dispersing agent in artificially sweetened gelatin desserts and in artificially sweetened gelatin dessert mixes, whereby the amount of the additive does not exceed 0.5 percent on a dry-weight basis.

(14) As an emulsifier in chocolate flavored syrups, whereby the maximum amount of the additive does not exceed 0.05 percent in the finished product.

(15) As a surfactant and wetting agent for natural and artificial colors in food as follows:

(i) In powdered soft drink mixes in an amount not to exceed 4.5 percent by weight of the mix.

(ii) In sugar-based gelatin dessert mixes in an amount not to exceed 0.5 percent by weight of the mix.

(iii) In artificially sweetened gelatin dessert mixes in an amount not to exceed 3.6 percent by weight of the mix.

(iv) In sugar-based pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

(v) In artificially sweetened pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 25, 1978; 45 FR 58836, Sept. 5, 1980; 46 FR 8466, Jan. 27, 1981]

§ 172.838 Polysorbate 65.

The food additive polysorbate 65 (polyoxyethylene (20) sorbitan tristearate), which is a mixture of polyoxyethylene ethers of mixed stearic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 15 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 88–98.
Acid number 0–2.
Hydroxyl number 44–60.
Oxyethylene content 46 percent–50 percent.

(c) The additive is used, or intended for use, as follows:

(1) As an emulsifier in ice cream, frozen custard, ice milk, fruit sherbet and nonstandardized frozen desserts when used alone or in combination with polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Sorbitan monostearate.
(ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the cake or cake mix, on a dry-weight basis. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.61 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;
(ii) Polysorbate 60;
(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

(4) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Sorbitan monostearate.
(ii) Polysorbate 60.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Sorbitan monostearate.
(ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the weight of the cake icing or cake filling. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.7 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978]

§ 172.840 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate), which is a mixture of polyoxyethylene ethers of mixed partial oleic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting oleic acid (usually containing associated fatty acids) with sorbitol to yield a product with a maximum acid number of 7.5 and a maximum water content of 0.5 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45–55.

Acid number 0-2.
Hydroxyl number 65-80.
Oxyethylene content 65 percent-69.5 percent.

(c) The additive is used or intended for use as follows:

(1) An emulsifier in ice cream, frozen custard, ice milk, fruit sherbet, and nonstandardized frozen desserts, when used alone or in combination with polysorbate 65 whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) In yeast-defoamer formulations whereby the maximum amount of the additive does not exceed 4 percent of the finished yeast defoamer and the maximum amount of the additive in the yeast from such use does not exceed 4 parts per million.

(3) As a solubilizing and dispersing agent in pickles and pickle products, whereby the maximum amount of the additive does not exceed 500 parts per million.

(4) As a solubilizing and dispersing agent in:

(i) Vitamin-mineral preparations containing calcium caseinate in the absence of fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 175 milligrams from the recommended daily dose of the preparations.

(ii) Fat-soluble vitamins in vitamin and vitamin-mineral preparations containing no calcium caseinate, whereby the maximum intake of polysorbate 80 shall not exceed 300 milligrams from the recommended daily dose of the preparations.

(iii) In vitamin-mineral preparations containing both calcium caseinate and fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 475 milligrams from the recommended daily dose of the preparations.

(5) As a surfactant in the production of coarse crystal sodium chloride whereby the maximum amount of the additive in the finished sodium chloride does not exceed 10 parts per million.

(6) In special dietary foods, as an emulsifier for edible fats and oils, with directions for use which provide for the ingestion of not more than 360 milligrams of polysorbate 80 per day.

(7) As a solubilizing and dispersing agent for dill oil in canned spiced green beans, not to exceed 30 parts per million.

(8) As an emulsifier, alone or in combination with polysorbate 60, in shortenings and edible oils intended for use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 60 in any combination providing no more than 1 percent of polysorbate 80 and no more than 1 percent of polysorbate 60, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1-percent limitation specified in paragraph (c)(8) (i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;
(ii) Polysorbate 60;
(iii) Polysorbate 65;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

(10) It is used as a wetting agent in scald water for poultry defeathering, followed by potable water rinse. The concentration of the additive in the scald water does not exceed 0.0175 percent.

(11) As a dispersing agent in gelatin desserts and in gelatin dessert mixes, whereby the amount of the additive does not exceed 0.082 percent on a dry-weight basis.

(12) As an adjuvant added to herbicide use and plant-growth regulator use dilutions by a grower or applicator prior to application of such dilutions to the growing crop. Residues resulting from such use are exempt from the requirement of a tolerance. When

so used or intended for use, the additive shall be exempt from the requirements of paragraph (d)(1) of this section.

(13) As a defoaming agent in the preparation of the creaming mixture for cottage cheese and lowfat cottage cheese, as identified in §§ 133.128 and 133.131 of this chapter, respectively, whereby the amount of the additive does not exceed .008 percent by weight of the finished products.

(14) As a surfactant and wetting agent for natural and artificial colors for use in barbecue sauce where the level of the additive does not exceed 0.005 percent by weight of the barbecue sauce.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978; 45 FR 58835, Sept. 5, 1980; 46 FR 8466, Jan. 27, 1981]

§ 172.841 Polydextrose.

Polydextrose as identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a)(1) Polydextrose (CAS Reg. No. 68424-04-4) is a partially metabolizable water-soluble polymer prepared by the condensation of a melt which consists of approximately 89 percent D-glucose, 10 percent sorbitol and 1 percent citric acid, on a weight basis.

(2) Polydextrose may be partially neutralized with potassium hydroxide.

(b) It is used in accordance with good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use: baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies; cakes; cookies; and similar baked products); chewing gum; confections and frostings; dressings for salads; frozen dairy desserts and mixes; gelatins, puddings, and fillings; and hard and soft candy.

(c) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with Part 105 of this chapter.

(d) The label and labeling of food a single serving of which would be expected to exceed 15 grams of the additive shall bear the statement: "Sensitive individuals may experience a laxative effect from excessive consumption of this product".

[46 FR 30081, June 5, 1981]

§ 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

Saponification number	147-157
Acid number	5-10
Hydroxyl number	235-260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Polysorbate 60;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with polysorbate 60 may be used in excess of 0.4 percent: *Provided,* That the amount of the additive does not exceed 0.27 percent and the amount of polysorbate 60 does not exceed 0.77 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.61 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.61 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of the emulsifiers shall exceed 0.66 percent of the weight of the cake or cake mix, calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with polysorbate 60 in nonstandardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with polysorbate 60 in any combination of up to 1 percent sorbitan monostearate and up to 0.5 percent polysorbate 60 provided that the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.7 percent of the weight of the cake icing or cake filling. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.7 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(5) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 60.

(ii) Polysorbate 65.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(6) It is used alone as a rehydration aid in the production of active dry yeast in an amount not to exceed 1 percent by weight of the dry yeast.

(7) As an emulsifier, alone or in combination with polysorbate 60, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with § 172.878 and/or petroleum wax conforming with § 172.886 for use as protective coatings on raw fruits and vegetables.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978]

§ 172.844 Calcium stearoyl-2-lactylate.

The food additive calcium stearoyl-2-lactylate may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of calcium salts of stearoyl lactylic acids and minor proportions of other calcium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the calcium salts.

(b) The additive meets the following specifications:

Acid number, 50-86.
Calcium content, 4.2-5.2 percent.
Lactic acid content, 32-38 percent.
Ester number, 125-164.

(c) It is used or intended for use as follows:

(1) As a dough conditioner in yeast-leavened bakery products and prepared mixes for yeast-leavened bakery products in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

(2) As a whipping agent in:

(i) Liquid and frozen egg white at a level not to exceed 0.05 percent.

(ii) Dried egg white at a level not to exceed 0.5 percent.

(iii) Whipped vegetable oil topping at a level not to exceed 0.3 percent of the weight of the finished whipped vegetable oil topping.

(3) As a conditioning agent in dehydrated potatoes in an amount not to exceed 0.5 percent by weight thereof.

(d) To assure safe use of the additive:

(1) The label and labeling of the food additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions of use to provide a finished food that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.846 Sodium stearoyl lactylate.

The food additive sodium stearoyl lactylate (CAS Reg. No. 25-383-997) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of sodium salts of stearoyl lactylic acids and minor proportions of sodium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the sodium salts.

(b) The additive meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 300-301, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) It is used or intended for use as follows when standards of identity established under section 401 of the Act do not preclude such use:

(1) As a dough strengthener, emulsifier, or processing aid in baked products, pancakes, and waffles, in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

(2) As a surface-active agent, emulsifier, or stabilizer in icings, fillings, puddings, and toppings, at a level not to exceed 0.2 percent by weight of the finished food.

(3) As an emulsifier or stabilizer in liquid and solid edible fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, at a level not to exceed 0.3 percent by weight of the finished edible fat-water emulsion.

(4) As a formulation aid, processing aid, or surface-active agent in dehydrated potatoes, in an amount not to exceed 0.5 percent of the dry weight of the food.

(5) As an emulsifier, stabilizer, or texturizer in snack dips, at a level not to exceed 0.2 percent by weight of the finished product.

(6) As an emulsifier, stabilizer, or texturizer in cheese substitutes and imitations and cheese product substitutes and imitations, at a level not to exceed 0.2 percent by weight of the finished food.

(7) As an emulsifier, stabilizer, or texturizer in sauces or gravies, and the products containing the same, in an amount not to exceed 0.25 percent by weight of the finished food.

(8) In prepared mixes for each of the foods listed in paragraphs (c) (1) through (7) of this section, provided the additive is used only as specified in each of those paragraphs.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[45 FR 51767, Aug. 5, 1980, as amended at 49 FR 10105, Mar. 19, 1984; 50 FR 49536, Dec.

3, 1985; 51 FR 1495, Jan. 14, 1986; 51 FR 3333, Jan. 27, 1986]

§ 172.848 Lactylic esters of fatty acids.

Lactylic esters of fatty acids may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from lactic acid and fatty acids meeting the requirements of § 172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of § 172.862.

(b) They are used as emulsifiers, plasticizers, or surface-active agents in the following foods, when standards of identity do not preclude their use:

Foods	Limitations
Bakery mixes	
Baked products	
Cake icings, fillings, and toppings.	
Dehydrated fruits and vegetables	
Dehydrated fruit and vegetable juices.	
Edible vegetable fat-water emulsions.	As substitutes for milk or cream in beverage coffee.
Frozen desserts	
Liquid shortening	For household use.
Pancake mixes	
Precooked instant rice	
Pudding mixes	

(c) They are used in an amount not greater than required to produce the intended physical or technical effect, and they may be used with shortening and edible fats and oils when such are required in the foods identified in paragraph (b) of this section.

§ 172.850 Lactylated fatty acid esters of glycerol and propylene glycol.

The food additive lactylated fatty acid esters of glycerol and propylene glycol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of esters produced by the lactylation of a product obtained by reacting edible fats or oils with propylene glycol.

(b) The additive meets the following specifications: Water insoluble combined lactic acid, 14-18 percent; and acid number, 12 maximum.

(c) It is used in amounts not in excess of that reasonably required to produce the intended physical effect as an emulsifier, plasticizer, or surface-active agent in food.

§ 172.852 Glyceryl-lacto esters of fatty acids.

Glyceryl-lacto esters of fatty acids (the lactic acid esters of mono- and diglycerides) may be safely used in food in accordance with the following prescribed conditions:

(a) They are manufactured from glycerin, lactic acid, and fatty acids conforming with § 172.860 and/or oleic acid derived from tall oil fatty acids conforming with § 172.862 and/or edible fats and oils.

(b) They are used in amounts not in excess of those reasonably required to accomplish their intended physical or technical effect as emulsifiers and plasticizers in food.

§ 172.854 Polyglycerol esters of fatty acids.

Polyglycerol esters of fatty acids, up to and including the decaglycerol esters, may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from corn oil, cottonseed oil, lard, palm oil from fruit, peanut oil, safflower oil, sesame oil, soybean oil, and tallow and the fatty acids derived from these substances (hydrogenated and nonhydrogenated) meeting the requirements of § 172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of § 172.862.

(b) They are used as emulsifiers in food, in amounts not greater than that required to produce the intended physical or technical effect.

(c) Polyglycerol esters of a mixture of stearic, oleic, and coconut fatty acids are used as a cloud inhibitor in vegetable and salad oils when use is not precluded by standards of identity. The fatty acids used in the production of the polyglycerol esters meet the requirements of § 172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform its cloud-inhibiting effect. Oleic acid derived from tall oil fatty acids conforming with § 172.862 may be used as a substitute for or together with the oleic acid permitted by this paragraph.

(d) Polyglycerol esters of butter oil fatty acids are used as emulsifiers in combination with other approved emulsifiers in dry, whipped topping base. The fatty acids used in the production of the polyglycerol esters meet the requirements of § 172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform their emulsifying effect.

§ 172.856 Propylene glycol mono- and diesters of fats and fatty acids.

Propylene glycol mono- and diesters of fats and fatty acids may be safely used in food, subject to the following prescribed conditions:

(a) They are produced from edible fats and/or fatty acids in compliance with § 172.860 and/or oleic acid derived from tall oil fatty acids in compliance with § 172.862.

(b) They are used in food in amounts not in excess of that reasonably required to produce their intended effect.

§ 172.858 Propylene glycol alginate.

The food additive propylene glycol alginate (CAS Reg. No. 9005-37-2) may be used as an emulsifier, flavoring adjuvant, formulation aid, stabilizer, surfactant, or thickener in foods in accordance with the following prescribed conditions:

(a) The additive meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 256, which is incorporated by reference (copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and the additional specification that it shall have up to 85 percent of the carboxylic acid groups esterified with the remaining groups either free or neutralized.

(b) The additive is used or intended for use in the following foods as defined in § 170.3(n) of this chapter, when standards of identity established under section 401 of the act do not preclude such use:

(1) As a stabilizer in frozen dairy desserts, in fruit and water ices, and in confections and frostings at a level not to exceed 0.5 percent by weight of the finished product.

(2) As an emulsifier, flavoring adjuvant, stabilizer, or thickener in baked goods at a level not to exceed 0.5 percent by weight of the finished product.

(3) As an emulsifier, stabilizer, or thickener in cheeses at a level not to exceed 0.9 percent by weight of the finished product.

(4) As an emulsifier, stabilizer, or thickener in fats and oils at a level not to exceed 1.1 percent by weight of the finished product.

(5) As an emulsifier, stabilizer, or thickener in gelatins and puddings at a level not to exceed 0.6 percent by weight of the finished product.

(6) As a stabilizer or thickener in gravies and in sweet sauces at a level not to exceed 0.5 percent by weight of the finished product.

(7) As a stabilizer in jams and jellies at a level not to exceed 0.4 percent by weight of the finished product.

(8) As an emulsifier, stabilizer, or thickener in condiments and relishes at a level not to exceed 0.6 percent by weight of the finished product.

(9) As a flavoring adjunct or adjuvant in seasonings and flavors at a level not to exceed 1.7 percent by weight of the finished product.

(10) As an emulsifier, flavoring adjuvant, formulation aid, stabilizer or thickener, or surface active agent in other foods, where applicable, at a level not to exceed 0.3 percent by weight of the finished product.

(c) To ensure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, "propylene glycol alginate" or "propylene glycol ester of alginic acid".

(2) Adequate directions for use.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

[47 FR 29950, July 9, 1982]

§ 172.859 Sucrose fatty acid esters.

Sucrose fatty acid esters identified in this section may be safely used in accordance with the following prescribed conditions:

(a) Sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow. The only solvents which may be used in the preparation of sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters.

(b) Sucrose fatty acid esters meet the following specifications:

(1) The total content of mono-, di-, and tri-esters is not less than 80 percent as determined by a method title "Sucrose Fatty Acid Esters, Method of Assay," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The free sucrose content is not more than 5 percent as determined by Test S.2 in the method titled "Sucrose Fatty Acid Esters, Method of Assay," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(3) The acid value is not more than 6.

(4) The residue on ignition (sulfated ash) is not more than 2 percent.

(5) The total ethyl acetate content is not more than 350 parts per million as determined by a method titled "Determination of Ethyl Acetate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(6) Arsenic is not more than 3 parts per million.

(7) Total heavy metal content (as Pb) is not more than 50 parts per million.

(8) Lead is not more than 10 parts per million.

(9) The total content of methyl ethyl ketone or of methanol shall not be more than 10 parts per million as determined by a method titled "Methyl Ethyl Ketone Test; Methyl Alcohol Test," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(10) The total dimethyl sulfoxide content is not more than 2 parts per million as determined by a method entitled "Determination of Dimethyl Sulfoxide," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register 1100 L St. NW., Washington, DC 20408.

(11) The total isobutyl alcohol (2-methyl-1-propanol) content is not more than 10 parts per million as determined by a method entitled "Determination of Isobutyl Alcohol," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) Sucrose fatty acid esters may be used as follows when standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use:

(1) As emulsifiers as defined in § 170.3(o)(8) of this chapter or as sta-

bilizers as defined in § 170.3(o)(28) of this chapter in baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter, in dairy product analogs as defined in § 170.3(n)(10) of this chapter, in frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, and in whipped milk products.

(2) As texturizers as defined in § 170.3(o)(32) of this chapter in biscuit mixes.

(3) As components of protective coatings applied to fresh apples, bananas, pears, and pineapples to retard ripening and spoiling.

(d) Sucrose fatty acid esters are used in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended effect.

[47 FR 55475, Dec. 10, 1982, as amended at 48 FR 38226, 38227, Aug. 23, 1983; 51 FR 40161, Nov. 5, 1986]

§ 172.860 Fatty acids.

The food additive fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The food additive consists of one or any mixture of the following straight-chain monobasic carboxylic acids and their associated fatty acids manufactured from fats and oils derived from edible sources: Capric acid, caprylic acid, lauric acid, myristic acid, oleic acid, palmitic acid, and stearic acid.

(b) The food additive meets the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) It is free of chick-edema factor:

(i) As evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (c)(2) of this section; or

(ii) As evidenced by the absence of chromatographic peaks with a retention time relative to aldrin (RA) between 10 and 25, using the gas chromatographic-electron capture method prescribed in paragraph (c)(3) of this section. If chromatographic peaks are found with RA values between 10 and 25, the food additive shall meet the requirements of the bioassay method prescribed in paragraph (c)(2) of this section for determining chick-edema factor.

(c) For the purposes of this section:

(1) Unsaponifiable matter shall be determined by the method described in the 13th Ed. (1980) of the "Official Methods of Analysis of the Association of Official Analytical Chemists," which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Chick-edema factor shall be determined by the bioassay method described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 28.127-28.130, which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) The gas chromatographic-electron capture method for testing fatty acids for chick-edema shall be the method described in the "Journal of the Association of Official Analytical Chemists," Volume 50 (No. 1), pages 216-218 (1967), or the modified method using a sulfuric acid clean-up procedure, as described in the "Journal of the Association of the Offical Analytical Chemists," Volume 51 (No. 2), pages 489-490 (1968), which are incorporated by reference. See paragraph (c)(2) of this section for availability of these references.

(d) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and as a defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The common or usual name of the acid or acids contained therein.

(2) The words "food grade", in juxtaposition with and equally as prominent as the name of the acid.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984]

§ 172.862 Oleic acid derived from tall oil fatty acids.

The food additive oleic acid derived from tall oil fatty acids may be safely used in food and as a component in the manufacture of food-grade additives in accordance with the following prescribed conditions:

(a) The additive consists of purified oleic acid separated from refined tall oil fatty acids.

(b) The additive meets the following specifications:

(1) Specifications for oleic acid prescribed in the "Food Chemicals Codex," 3d Ed. (1981), pp. 207-208, which is incorporated by reference, except that titer (solidification point) shall not exceed 13.5° C and unsaponifiable matter shall not exceed 0.5 percent. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The resin acid content does not exceed 0.01 as determined by ASTM method D1240-82, "Standard Test Method for Rosin Acids in Fatty Acids," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) The requirements for absence of chick-edema factor as prescribed in § 172.860.

(c) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(d) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The common or usual name of the acid.

(2) The words "food grade" in juxtaposition with and equally as prominent as the name of the acid.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.863 Salts of fatty acids.

The food additive salts of fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The additive consists of one or any mixture of two or more of the aluminum, calcium, magnesium, potassium, and sodium salts of the fatty acids conforming with § 172.860 and/or oleic acid derived from tall oil fatty acids conforming with § 172.862.

(b) The food additive is used or intended for use as a binder, emulsifier, and anticaking agent in food in accordance with good manufacturing practice.

(c) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The common or usual name of the fatty acid salt or salts contained therein.

(2) The words "food grade", in juxtaposition with and equally as prominent as the name of the salt.

§ 172.864 Synthetic fatty alcohols.

Synthetic fatty alcohols may be safely used in food and in the synthesis of food components in accordance with the following prescribed conditions:

(a) The food additive consists of any one of the following fatty alcohols:

(1) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation and hydrolysis of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C_2H_4), and utilizing the hydrocarbon solvent as defined in paragraph (b) of this section, such that:

(i) Hexyl, octyl, decyl, lauryl, and myristyl alcohols contain not less than 99 percent of total alcohols and not less than 96 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(ii) Cetyl and stearyl alcohols contain not less than 98 percent of total alcohols and not less than 94 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(iii) The synthetic fatty alcohols contain no more than 0.1 weight percent of total diols as determined by a method available upon request from the Commissioner of Food and Drugs.

(2) Hexyl, octyl, and decyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation, hydrolysis, and catalytic hydrogenation (catalyst consists of copper, chromium, and nickel) of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C_2H_4), and utilizing an external coolant such that these alcohols meet the specifications prescribed in paragraph (a)(1) (i) and (iii) of this section.

(b) The hydrocarbon solvent used in the process described in paragraph (a)(1) of this section is a mixture of liquid hydrocarbons essentially paraffinic in nature, derived from petroleum and refined to meet the specifications described in paragraph (b)(1) of this section when subjected to the procedures described in paragraph (b) (2) and (3) of this section.

(1) The hydrocarbon solvent meets the following specifications:

(i) Boiling-point range: 175° C-275° C.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (millicrons)	Maximum absorbance per centimeter optical path length
280-289	0.15
290-299	.12
300-359	.05
360-400	.02

(2) Use ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference, to determine boiling point range. Copies of the material incorporated by reference may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) The analytical method for determining ultraviolet absorbance limits is as follows:

GENERAL INSTRUCTIONS

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of hydrocarbon solvent samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Chromatographic tube. 450 millimeters in length (packing section), inside diameter 19 millimeters ± 1 millimeter, equipped with a wad of clean Pyrex brand filtering wool (Corning Glass Works Catalog No. 3950 or equivalent). The tube shall contain a 250-milliliter reservoir and a 2-millimeter tetrafluoroethylene polymer stopcock at the opposite end. Overall length of the tube is 670 millimeters.

Stainless steel rod. 2 feet in length, 2 to 4 millimeters in diameter.

Vacuum oven. Similar to Labline No. 3610 but modified as follows: A copper tube one-fourth inch in diameter and 13 inches in length is bent to a right angle at the 4-inch point and plugged at the opposite end; eight copper tubes one-eighth inch in diameter and 5 inches in length are silver soldered in drilled holes (one-eighth inch in diameter) to the one-fourth-inch tube, one on each side at the 5-, 7.5-, 10- and 12.5-inch points; the one-eighth-inch copper tubes are bent to conform with the inner periphery of the oven.

Beakers. 250-milliliter and 500-milliliter capacity.

Graduated cylinders. 25-milliliter, 50-milliliter, and 150-milliliter capacity.

Tuberculin syringe. 1-milliliter capacity, with 3-inch, 22-gauge needle.

Volumetric flask. 5-milliliter capacity.

Spectrophotometric cells. Fused quartz ground glass stoppered cells, optical path length in the range of 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less: under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, hexane, and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate in the vacuum oven under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 5-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 5 milliliters volume. Determine the absorbance in the 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.02 per centimeter path length between 280 and 300 mμ and shall not exceed 0.01 per centimeter path length between 300 and 400 mμ.

Isooctane (2,2,4-trimethylpentane). Use 10 milliliters for the test described in the preceding paragraph. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent).

Benzene, spectro grade (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 80 milliliters for the test. If necessary, benzene may be purified by distillation or otherwise.

Hexane, spectro grade (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 650 milliliters for the test. If necessary, hexane may be purified by distillation or otherwise.

1,2-Dichloroethane, spectro grade (Matheson, Coleman, and Bell, East Rutherford, N.J., or equivalent). Use 20 milliliters for test. If necessary, 1,2-dichloroethane may be purified by distillation.

Eluting mixtures:

1. *10 percent 1,2-dichloroethane in hexane.* Pipet 100 milliliters of 1,2-dichloroethane into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

2. *40 percent benzene in hexane.* Pipet 400 milliliters of benzene into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 5 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference between 280 mμ-

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[1] As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

400mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. If necessary, *n*-hexadecane may be purified by percolation through activated silica gel or by distillation.

Silica gel, 28-200 mesh (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent). Activate as follows: Weigh about 900 grams into a 1-gallon bottle, add 100 milliliters of de-ionized water, seal the bottle and shake and roll at intervals for 1 hour. Allow to equilibrate overnight in the sealed bottle. Activate the gel at 150° C for 16 hours, in a 2-inch × 7-inch × 12-inch porcelain pan loosely covered with aluminum foil, cool in a dessicator, transfer to a bottle and seal.

PROCEDURE

Determination of ultraviolet absorbance. Before proceeding with the analysis of a sample determine the absorbance in a 1-centimeter path cell for the reagent blank by carrying out the procedure without a sample. Record the absorbance in the wavelength range of 280 to 400 millimicrons. Typical reagent blank absorbance in this range should not exceed 0.04 in the 280 to 299 millimicron range, 0.02 in the 300 to 359 millimicron range, and 0.01 in the 360 to 400 millimicron range. If the characteristic benzene peaks in the 250 to 260 millimicron region are present, remove the benzene by the procedure described above under "Reagents and Materials," "Organic Solvents," and record absorbance again.

Transfer 50 grams of silica gel to the chromatographic tube for sample analysis. Raise and drop the column on a semisoft, clean surface for about 1 minute to settle the gel. Pour 100 milliliters of hexane into the column with the stopcock open and allow to drain to about one-half inch above the gel. Turn off the stopcock and allow the column to cool for 30 minutes. After cooling, vibrate the column to eliminate air and stir the top 1 to 2 inches with a small diameter stainless steel rod. Take care not to get the gel above the liquid and onto the sides of the column.

Weigh out 40 grams ±0.1 gram of the hydrocarbon solvent sample into a 250-milliliter beaker, add 50 milliliters of hexane, and pour the solution into the column. Rinse the beaker with 50 milliliters of hexane and add this to the column. Allow the hexane sample solution to elute into a 500-milliliter beaker until the solution is about one-half inch above the gel. Rinse the column three times with 50-milliliter portions of hexane. Allow each hexane rinse to separately elute to about one-half inch above the gel. Replace the eluate beaker (discard the hexane eluate) with a 250-milliliter beaker. Add two separate 25-milliliter portions of 10 percent 1,2-dichloroethane and allow each to separately elute as before. Finally, add 150 milliliters of 10 percent 1,2-dichloroethane for a total of 200 milliliters. When the final 10 percent 1,2-dichloroethane fraction is about one-half inch above the top of the gel bed, replace the receiving beaker (discard the 1,2-dichloroethane eluate) with a 250-milliliter beaker containing 1 milliliter of hexadecane. Adjust the elution rate to 2 to 3 milliliters per minute, add two 25-milliliter portions of 40 percent benzene and allow each to separately elute as before to within about one-half inch of the gel bed. Finally, add 150 milliliters of 40 percent benzene for a total of 200 milliliters. Evaporate the benzene in the oven with vacuum and sufficient nitrogen flow to just ripple the top of the benzene solution. When the benzene is removed (as determined by a constant volume of hexadecane) add 5 milliliters of isooctane and evaporate. Repeat once to insure complete removal of benzene. Remove the beaker and cover with aluminum foil (previously rinsed with hexane) until cool.

Quantitatively transfer the hexadecane residue to a 5-milliliter volumetric flask and dilute to volume with isooctane. Determine the absorbance of the solution in 1-centimeter path length cells between 280 and 400 millimicrons using isooctane as a reference. Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a sample. If the corrected absorbance does not exceed the limits prescribed in paragraph (b)(1)(ii) of this section, the sample meets the ultraviolet absorbance specifications for hydrocarbon solvent.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or Part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984]

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC_2H_5) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as follows:

(1) As a binder and filler in dry vitamin preparations.

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.

§ 172.870 Hydroxypropyl cellulose.

The food additive hydroxypropyl cellulose may be safely used in food, except standardized foods that do not provide for such use, in accordance with the following prescribed conditions:

(a) The additive consists of one of the following:

(1) A cellulose ether containing propylene glycol groups attached by an ether linkage which contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 145 centipoises for 10 percent by weight aqueous solution at 25° C.

(2) A cellulose ether containing propylene glycol groups attached by an ether linkage having a hydroxypropoxy (OC_3H_6OH) content of 5 to 16 percent weight in weight (w/w) on an anhydrous basis, i.e., 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit. The common name for this form of the additive is low substituted hydroxypropyl cellulose.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(2) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is used in accordance with good manufacturing practice.

[46 FR 50065, Oct. 9, 1981]

§ 172.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula $[C_6H_{(10-x-y)}O_5(CH_3)_x(C_2H_5)_y]_n$, where x is the number of methyl groups and y is the number of ethyl groups. The average value of x is 0.3 and the average value of y is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH_3, and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC_2H_5, both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20° C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004-65-3) may be safely used in food, except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

(b) The additive is used or intended for use as follows:

Use and Limitations

Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.

Vitamin and mineral tablets—As a component of protective coatings.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the "Journal of the Association of Official Analytical Chemists," Volume 45, page 66 (1962), which is incorporated by reference, after correction of the ultraviolet absorbance for any absorbance due to added antioxidants. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
1. As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery.	Not to exceed 0.6% of the capsule or tablet.
2. As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.	Not to exceed 0.6% of the capsule or tablet.
3. As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
4. As a defoamer in food	In accordance with § 173.340 of this chapter.
5. In bakery products, as a release agent and lubricant	Not to exceed 0.15% of bakery products.
6. In dehydrated fruits and vegetables, as a release agent	Not to exceed 0.02% of dehydrated fruits and vegetables.
7. In egg white solids, as a release agent	Not to exceed 0.1% of egg white solids.

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
8. On raw fruits and vegetables, as a protective coating	In an amount not to exceed good manufacturing practice.
9. In frozen meat, as a component of hot-melt coating	Not to exceed 0.095% of meat.
10. As a protective float on brine used in the curing of pickles	In an amount not to exceed good manufacturing practice.
11. In molding starch used in the manufacture of confectionery	Not to exceed 0.3 percent in the molding starch.
12. As a release agent, binder, and lubricant in the manufacture of yeast	Not to exceed 0.15 percent of yeast.
13. As an antidusting agent in sorbic acid for food use	Not to exceed 0.25 percent in the sorbic acid.
14. As release agent and as sealing and polishing agent in the manufacture of confectionery.	Not to exceed 0.2 percent of confectionery.
15. As a dust control agent for wheat, corn, soybean, barley, rice, rye, oats, and sorghum.	Applied at a level of no more than 0.02 percent by weight of grain.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 8764, Mar. 2, 1982; 47 FR 11838, Mar. 19, 1982; 48 FR 55728, Dec. 15, 1983; 49 FR 10105, Mar. 19, 1984]

§ 172.880 Petrolatum.

Petrolatum may be safely used in food, subject to the provisions of this section.

(a) Petrolatum complies with the specifications set forth in the United States Pharmacopeia XX (1980) for white petrolatum or in the National Formulary XV (1980) for petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b):

Ultraviolet absorbance per centimeter path length:

Millimicrons	Maximum
280-289	0.25
290-299	.20
300-359	.14
360-400	.04

(c) Petrolatum is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)
In bakery products; as release agent and lubricant	With white mineral oil, not to exceed 0.15 percent of bakery product.
In confectionery; as release agent and as sealing and polishing agent	Not to exceed 0.2 percent of confectionery.
In dehydrated fruits and vegetables; as release agent	Not to exceed 0.02 percent of dehydrated fruits and vegetables.
In egg white solids; as release agent	Not to exceed 0.1 percent of egg white solids.
On raw fruits and vegetables; as protective coating	In an amount not to exceed good manufacturing practice.
In beet sugar and yeast; as defoaming agent	As prescribed in § 173.340 of this chapter.

(d) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.882 Synthetic isoparaffinic petroleum hydrocarbons.

Synthetic isoparaffinic petroleum hydrocarbons may be safely used in food, in accordance with the following conditions:

(a) They are produced by synthesis from petroleum gases and consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 93-260° C as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Ultraviolet absorbance:

260-319 millimicrons—1.5 maximum.

320-329 millimicrons—0.08 maximum.

330-350 millimicrons—0.05 maximum.

Nonvolatile residual: 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application of mineral oil, disregarding the last sentence of the procedure, under "Specifications" on page 66 of the *Journal of the Association of Official Analytical Chemists*, Volume 45 (February 1962), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. For hydrocarbons boiling below 250° F, the nonvolatile residue shall be determined by ASTM method D1353-78, "Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;" for those boiling above 121° C, ASTM method D381-80, "Standard Test Method for Existent Gum in Fuels by Jet Evaporation" shall be used. These methods are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect nor to exceed any prescribed limitations.

(c) Synthetic isoparaffinic petroleum hydrocarbons are used or intended for use as follows:

Uses	Limitations
1. In the froth-flotation cleaning of vegetables.	In an amount not to exceed good manufacturing practice.
2. As a component of insecticide formulations for use on processed foods.	Do.
3. As a component of coatings on fruits and vegetables.	Do.
4. As a coating on shell eggs	Do.
5. As a float on fermentation fluids in the manufacture of vinegar and wine and on brine used in curing pickles, to prevent or retard access of air, evaporation, and contamination with wild organisms during fermentation.	Do.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984]

§ 172.884 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used in food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

(1) Odor is faint and not kerosenic.

(2) Initial boiling point is 300° F minimum.

(3) Final boiling point is 650° F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii) of this chapter, as follows:

Wavelength mμ	Maximum absorbance per centimeter optical pathlength
280-289	4.0
290-299	3.3
300-329	2.3
330-360	.8

(c) The additive is used as follows:

Use	Limitations
As a coating on shell eggs	In an amount not to exceed good manufacturing practice.
As a defoamer in processing beet sugar and yeast.	Complying with § 173.340 of this chapter.
As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
In the froth-flotation cleaning of vegetables.	Do.
As a component of insecticide formulations used in compliance with regulations issued in Parts 170 through 189 of this chapter.	Do.

§ 172.886 Petroleum wax.

Petroleum wax may be safely used in or on food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed by this section.

(b) Petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in this paragraph.

	Maximum ultraviolet absorbance per centimeter path length
280-289 millimicrons	0.15
290-299 millimicrons	0.12
300-359 millimicrons	0.08
360-400 millimicrons	0.02

ANALYTICAL SPECIFICATION FOR PETROLEUM WAX

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ±0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately $\frac{3}{16}$-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jacket. Conical, for 500-milliliter separatory funnel. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide); 2-

liter distillation flask with heating mantle: Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5.000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons-400 millimicrons with spectral slit width of 2 millimicrons or less, under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a) loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. *10 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 500-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. *20 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask, and adjust to volume with isooctane, with mixing.

3. *Acetone-benzene-water mixture.* Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 mμ-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Pure grade, clear, water-white, m.p. 18° minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500-milliliter separatory funnel, mix and allow to cool for 5-10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40-milliliter extractives three times with 50-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate under* "Reagents and Materials" for preparation of filter), into a 250-milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40-milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash the second and first separatory funnels successively with a 10-milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25-milliliter volume. Determine the absorbance in 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution should not exceed 0.02 per centimeter path length in the 280 mμ-400 mμ range. (NOTE.—Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.)

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[1] As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2-liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50 grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrafluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the filtrate to a 2-liter separatory funnel and draw off the dimethyl sulfoxide into the 2-liter distillation flask of the vacuum distillation assembly and distill at approximately 3-millimeter Hg pressure or less. Discard the first 200-milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until approximately 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stoppered bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the absorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the absorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the absorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160° C ±1°C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized absorbent between 60-180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns-Manville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60-180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160° C ± 1° C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 mμ and 400 mμ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 mμ and 400 mμ for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter path length following the extraction stage should not exceed 0.040 in the wavelength range from 280 mμ to 400 mμ; the absorbance per centimeter path length following the complete procedure should not exceed 0.070 in the wavelength range from 280 mμ to 299 mμ, inclusive, nor 0.045 in the wavelength range from 300 mμ to 400 mμ. If in either spectrum the characteristic benzene peaks in the 250 mμ-260 mμ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Place a representative 1-kilogram sample of wax, or if this amount is not available, the entire sample, in a beaker of a capacity about three times the volume of the sample and heat with occasional stirring on a steam bath until the wax is completely melted and homogeneous. Weigh four 25-gram ±0.2 gram portions of the melted wax in separate 100-milliliter beakers. Reserve three of the portions for later replicate analyses as necessary. Pour one weighed portion immediately after remelting (on the steam bath) into a 500-milliliter separatory funnel containing 100 milliliters of the preequilibrated sulfoxide-phosphoric acid mixture that has been heated in the heating jacket at a temperature just high enough to keep the wax melted. (NOTE: In preheating the sulfoxide-acid mixture, remove the stopper of the separatory funnel at intervals to release the pressure.)

Promptly complete the transfer of the sample to the funnel in the jacket with portions of the preequilibrated isooctane, warming the beaker, if necessary, and using a total volume of just 50 milliliters of the solvent. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium Sulfate* under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 5-centimeter path length cells compared to isooctane as reference between 280 mμ-400 mμ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a wax sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter path length exceeds the limits prescribed in this paragraph (b), proceed as follows:

Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2-3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weight out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off of the column is between 2-3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (CAUTION: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2-3 milliliter per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to elute the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate prewashed with benzene (see *Sodium sulfate* under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic Solvents." Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 5-centimeter path length cells compared to isooctane as reference between 250 mμ-400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ-260mμ region, evaporate the solution to remove benzene by the procedure under "Organic Solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications.

(c) Petroleum wax may contain one or more of the following adjuvants in amounts not greater than that required to produce their intended effect:

(1) Antioxidants permitted in food by regulations issued in accordance with section 409 of the act.

(2) Poly(alkylacrylate) (CAS Reg. No. 27029-57-8), made from long chain (C_{16}-C_{22}) alcohols and acrylic acid, having: (i) A number average molecular weight between 40,000 and 100,000; (ii) a weight average molecular weight (MW_w) to number average molecular weight (MW_n) ratio (MW_w/MW_n) of not less than 3; and (iii) unreacted alkylacrylate monomer content not in excess of 14 percent, as determined by a method entitled, "Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax," which is incorporated by reference (copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408). Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) residues as determined by a method entitled, "Method for Determining Residual Level of Poly(alkylacrylate) in Petroleum Wax," which is incorporated by reference. Copies are available from the address cited in this paragraph (c)(2).

(d) Petroleum wax is used or intended for use as follows:

Use	Limitations
In chewing gum base, as a masticatory substance	In an amount not to exceed good manufacturing practice.
On cheese and raw fruits and vegetables as a protective coating.	Do.
As a defoamer in food	In accordance with § 173.340 of this chapter.
As a component of microcapsules for spice-flavoring substances	In accordance with § 172.230 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 48123, July 18, 1980; 47 FR 11838, Mar. 19, 1982; 50 FR 32561, Aug. 13, 1985; 51 FR 19544, May 30, 1986]

§ 172.888 Synthetic petroleum wax.

Synthetic petroleum wax may be safely used in or on foods in accordance with the following conditions:

(a) Synthetic petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, prepared by catalytic polymerization of ethylene, and refined to meet the specifications prescribed by this section.

(b) Synthetic petroleum wax meets the ultraviolet absorbance limits of § 172.886(b) when subjected to the analytical procedure described therein.

(c) Synthetic petroleum wax has a number average molecular weight of not less than 500 nor greater than 1,200 as determined by vapor pressure osmometry.

(d) Synthetic petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(e) Synthetic petroleum wax is used or intended for use as follows:

Use	Limitations
In chewing gum base, as a masticatory substance.	In accordance with § 172.615 in an amount not to exceed good manufacturing practice.
On cheese and raw fruits and vegetables as a protective coating.	In an amount not to exceed good manufacturing practice.

Use	Limitations
As a defoamer in food	In accordance with § 173.340 of this chapter.

§ 172.890 Rice bran wax.

Rice bran wax may be safely used in food in accordance with the following conditions:

(a) It is the refined wax obtained from rice bran and meets the following specifications:

Melting point 75° C to 80° C.
Free fatty acids, maximum 10 percent.
Iodine number, maximum 20.
Saponification number 75 to 120.

(b) It is used or intended for use as follows:

Food	Limitation in food	Use
Candy	50 p.p.m	Coating.
Fresh fruits and fresh vegetables.	do	Do.
Chewing gum	2½ pct	Plasticizing material.

§ 172.892 Food starch-modified.

Food starch-modified as described in this section may be safely used in food. The quantity of any substance employed to effect such modification shall not exceed the amount reasonably required to accomplish the intended physical or technical effect, nor exceed any limitation prescribed. To insure safe use of the food starch-modified, the label of the food additive container shall bear the name of the additive "food starch-modified" in addition to other information required by the Act. Food starch may be modified by treatment prescribed as follows:

(a) Food starch may be acid-modified by treatment with hydrochloric acid or sulfuric acid or both.

(b) Food starch may be bleached by treatment with one or more of the following:

	Limitations
Active oxygen obtained from hydrogen peroxide and/or peracetic acid, not to exceed 0.45 percent of active oxygen.	
Ammonium persulfate, not to exceed 0.075 percent and sulfur dioxide, not to exceed 0.05 percent.	
Chlorine, as calcium hypochlorite, not to exceed 0.036 percent of dry starch.	The finished food starch-modified is limited to use only as a component of batter for commercially processed foods.
Chlorine, as sodium hypochlorite, not to exceed 0.0082 pound of chlorine per pound of dry starch.	
Potassium permanganate, not to exceed 0.2 percent.	Residual manganese (calculated as Mn), not to exceed 50 parts per million in food starch-modified.
Sodium chlorite, not to exceed 0.5 percent.	

(c) Food starch may be oxidized by treatment with chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch.

(d) Food starch may be esterified by treatment with one of the following:

	Limitations
Acetic anhydride	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Adipic anhydride, not to exceed 0.12 percent, and acetic anhydride.	Do.
Monosodium orthophosphate	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
1-Octenyl succinic anhydride, not to exceed 3 percent.	
1-Octenyl succinic anhydride, not to exceed 2 percent, and aluminum sulfate, not to exceed 2 percent.	
Phosphorus oxychloride, not to exceed 0.1 percent.	
Phosphorus oxychloride, not to exceed 0.1 percent, followed by either acetic anhydride, not to exceed 8 percent, or vinyl acetate, not to exceed 7.5 percent.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Sodium trimetaphosphate	Residual phosphate in food starch-modified not to exceed 0.04 percent, calculated as phosphorus.
Sodium tripolyphosphate and sodium trimetaphosphate.	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
Succinic anhydride, not to exceed 4 percent.	

	Limitations
Vinyl acetate	Acetyl groups in food starch-modified not to exceed 2.5 percent.

(e) Food starch may be etherified by treatment with one of the following:

	Limitations
Acrolein, not to exceed 0.6 percent.	
Epichlorohydrin, not to exceed 0.3 percent.	
Epichlorohydrin, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent, added in combination or in any sequence.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.
Epichlorohydrin, not to exceed 0.1 percent, followed by propylene oxide, not to exceed 25 percent.	Do.
Propylene oxide, not to exceed 25 percent.	Do.

(f) Food starch may be esterified and etherified by treatment with one of the following:

	Limitations
Acrolein, not to exceed 0.6 percent and vinyl acetate, not to exceed 7.5 percent.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Epichlorohydrin, not to exceed 0.3 percent, and acetic anhydride.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Epichlorohydrin, not to exceed 0.3 percent, and succinic anhydride, not to exceed 4 percent.	
Phosphorus oxychloride, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.

(g) Food starch may be modified by treatment with one of the following:

	Limitations
Chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch; 0.45 percent of active oxygen obtained from hydrogen peroxide, and propylene oxide, not to exceed 25 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.
Sodium hydroxide, not to exceed 1 percent.	

(h) Food starch may be modified by a combination of the treatments prescribed by paragraphs (a) and/or (b) of this section and any one of the treatments prescribed by paragraph (c), (d), (e), (f), or (g) of this section, subject to any limitations prescribed by the paragraphs named.

(Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056, 72 Stat. 1784-1788 (21 U.S.C. 321(s) 342, 348, 371))

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 11697, Mar. 21, 1978; 46 FR 32015, June 19, 1981]

§ 172.894 Modified cottonseed products intended for human consumption.

The food additive modified cottonseed products may be used for human consumption in accordance with the following prescribed conditions:

(a) The additive is derived from:

(1) Decorticated, partially defatted, cooked, ground cottonseed kernels; or

(2) Decorticated, ground cottonseed kernels, in a process that utilizes *n*-hexane as an extracting solvent in such a way that no more than 60 parts per million of *n*-hexane residues and less than 1 percent fat by weight remain in the finished product; or

(3) Glandless cottonseed kernels roasted to attain a temperature of not less than 250° F in the kernel for not less than 5 minutes for use as a snack food, or in baked goods, or in soft candy; or

(4) Raw glandless cottonseed kernels may be used in hard candy where the kernel temperature during cooking will exceed 250° F for not less than 5 minutes.

(b) The additive is prepared to meet the following specifications:

(1) Free gossypol content not to exceed 450 parts per million.

(2) It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to other information required by the act, the name of the additive as follows:

(1) The additive identified in paragraph (a)(1) of this section as "partially defatted, cooked cottonseed flour".

(2) The additive identified in paragraph (a)(2) of this section as "defatted cottonseed flour".

(3) The additive identified in paragraph (a)(3) of this section as "roasted glandless cottonseed kernels".

(4) The additive identified in paragraph (a)(4) of this section as "raw glandless cottonseed kernels for use in cooked hard candy".

(d) The Food and Drug Administration and the Environmental Protection Agency have determined that glandless cottonseed kernels permitted for use by this section are a distinct commodity from glanded cottonseed.

§ 172.896 Dried yeasts.

Dried yeast (*Saccharomyces cerevisiae* and *Saccharomyces fragilis*) and dried torula yeast (*Candida utilis*) may be safely used in food provided the total folic acid content of the yeast does not exceed 0.04 milligram per gram of yeast (approximately 0.008 milligram of pteroylglutamic acid per gram of yeast).

§ 172.898 Bakers yeast glycan.

Bakers yeast glycan may be safely used in food in accordance with the following conditions:

(a) Bakers yeast glycan is the comminuted, washed, pasteurized, and dried cell walls of the yeast, *Saccharomyces cerevisiae*. It is composed principally of long chain carbohydrates, not less than 85 percent on a dry solids basis. The carbohydrate is composed of glycan and mannan units in approximately a 2:1 ratio.

(b) The additive meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
(1) In salad dressings as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Not to exceed a concentration of 5 percent of the finished salad dressing.
(2) In frozen dessert analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	In an amount not to exceed good manufacturing practice.
(3) In sour cream analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(4) In cheese spread analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(5) In cheese-flavored and sour cream flavored snack dips as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.

(e) The label and labeling of the ingredient shall bear adequate directions to assure that use of the ingredient complies with this regulation.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 58836, Sept. 5, 1980]

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Subpart A—Polymer Substances and Polymer Adjuvants for Food Treatment

Sec.

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173.350 Combustion product gas.
173.355 Dichlorodifluoromethane.
173.357 Materials used as fixing agents in the immobilization of enzyme preparations.
173.360 Octafluorocyclobutane.
173.385 Sodium methyl sulfate.
173.395 Trifluoromethane sulfonic acid.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055-1056, 72 Stat. 1785-1786 as amended (21 U.S.C. 348, 371), unless otherwise noted.

SOURCE: 42 FR 14526, Mar. 15, 1977, unless otherwise noted.

Subpart A—Polymer Substances and Polymer Adjuvants for Food Treatment

§ 173.5 Acrylate-acrylamide resins.

Acrylate-acrylamide resins may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1) Acrylamide-acrylic acid resin (hydrolyzed polyacrylamide) is produced by the polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid, with the greater part of the polymer being composed of acrylamide units.

(2) Sodium polyacrylate-acrylamide resin is produced by the polymerization and subsequent hydrolysis of acrylonitrile in a sodium silicate-sodium hydroxide aqueous solution, with the greater part of the polymer being composed of acrylate units.

(b) The additive contains not more than 0.05 percent of residual monomer calculated as acrylamide.

(c) The additive is used or intended for use as follows:

(1) The aditive identified in paragraph (a)(1) of this section is used as a flocculent in the clarification of beet sugar juice and liquor or cane sugar juice and liquor or corn starch hydrolyzate in an amount not to exceed 5 parts per million by weight of the juice or 10 parts per million by weight of the liquor or the corn starch hydrolyzate.

(2) The additive identified in paragraph (a)(2) of this section is used to control organic and mineral scale in beet sugar juice and liquor or cane sugar juice and liquor in an amount not to exceed 2.5 parts per million by weight of the juice or liquor.

[42 FR 14526, Mar. 15, 1977, as amended at 46 FR 30494, June 9, 1981]

§ 173.10 Modified polyacrylamide resin.

Modified polyacrylamide resin may be safely used in food in accordance with the following prescribed conditions:

(a) The modified polyacrylamide resin is produced by the copolymerization of acrylamide with not more than 5-mole percent β-methacrylyloxyethyltrimethylammonium methyl sulfate.

(b) The modified polyacrylamide resin contains not more than 0.05 percent residual acrylamide.

(c) The modified polyacrylamide resin is used as a flocculent in the clarification of beet or cane sugar juice in an amount not exceeding 5 parts per million by weight of the juice.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to the other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

§ 173.20 Ion-exchange membranes.

Ion-exchange membranes may be safely used in the processing of food under the following prescribed conditions:

(a) The ion-exchange membrane is prepared by subjecting a polyethylene base conforming to § 177.1520 of this chapter to polymerization with styrene until the polystyrene phase of the base is not less than 16 percent nor more than 30 percent by weight. The base is then modified by reaction with chloromethyl methyl ether, and by subsequent amination with trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine.

(b) The ion-exchange membrane is manufactured so as to comply with the following extraction limitations when subjected to the described procedure: Separate square-foot samples of membrane weighing approximately 14 grams each are cut into small pieces and refluxed for 4 hours in 150 cubic centimeters of the following solvents: Distilled water, 5 percent acetic acid, and 50 percent alcohol. Extraction from each sample will not exceed 0.4 percent by weight of sample.

(c) The ion-exchange membrane will be used in the production of grapefruit juice to adjust the ratio of citric acid to total solids of the grapefruit juice produced.

§ 173.25 Ion-exchange resins.

Ion-exchange resins may be safely used in the treatment of food under the following prescribed conditions:

(a) The ion-exchange resins are prepared in appropriate physical form, and consist of one or more of the following:

(1) Sulfonated copolymer of styrene and divinylbenzene.

(2) Sulfonated anthracite coal meeting the requirements of ASTM method D388-38, Class I, Group 2, "Standard Specifications for Classification of Coal by Rank," which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Sulfite-modified cross-linked phenol-formaldehyde, with modification resulting in sulfonic acid groups on side chains.

(4) Methacrylic acid-divinylbenzene copolymer.

(5) Cross-linked polystyrene, first chloromethylated then aminated with trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine.

(6) Diethylenetriamine, triethylenetetramine, or tetraethylenepentamine cross-linked with epichlorohydrin.

(7) Cross-linked phenol-formaldehyde activated with one or both of the following: Triethylene tetramine and tetraethylenepentamine.

(8) Reaction resin of formaldehyde, acetone, and tetraethylenepentamine.

(9) Completely hydrolyzed copolymers of methyl acrylate and divinylbenzene.

(10) Completely hydrolyzed terpolymers of methyl acrylate, divinylbenzene, and acrylonitrile.

(11) Sulfonated terpolymers of styrene, divinylbenzene, and acrylonitrile or methyl acrylate.

(12) Methyl acrylate-divinylbenzene copolymer containing not less than 2 percent by weight of divinylbenzene,

aminolyzed with dimethylaminopropylamine.

(13) Methyl acrylate-divinylbenzene copolymer containing not less than 3.5 percent by weight of divinylbenzene, aminolyzed with dimethylaminopropylamine.

(14) Epichlorohydrin cross-linked with ammonia.

(15) Sulfonated tetrapolymer of styrene, divinylbenzene, acrylonitrile, and methyl acrylate derived from a mixture of monomers containing not more than a total of 2 percent by weight of acrylonitrile and methyl acrylate.

(16) Methyl acrylate-divinylbenzene-diethylene glycol divinyl ether terpolymer containing not less than 3.5 percent by weight of divinylbenzene and not more than 0.6 percent by weight of diethylene glycol divinyl ether, aminolyzed with dimethylaminopropylamine.

(17) Styrene-divinylbenzene cross-linked copolymer, first chloromethylated then aminated with dimethylamine and oxidized with hydrogen peroxide whereby the resin contains not more than 15 percent by weight of vinyl *N,N*-dimethylbenzylamine-*N*-oxide and not more than 6.5 percent by weight of nitrogen.

(18) Methyl acrylate-divinylbenzene-diethylene glycol divinyl ether terpolymer containing not less than 7 percent by weight of divinylbenzene and not more than 2.3 percent by weight of diethylene glycol divinyl ether, aminolyzed with dimethylaminopropylamine and quaternized with methyl chloride.

(19) Epichlorohydrin cross-linked with ammonia and then quaternized with methyl chloride to contain not more than 18 percent strong base capacity by weight of total exchange capacity [Chemical Abstracts Service name: Oxirane (chloromethyl)-, polymer with ammonia, reaction product with chloromethane; CAS Reg. No. 68036-99-7].

(b) Ion-exchange resins are used in the purification of foods, including potable water, to remove undesirable ions or to replace less desirable ions with one or more of the following: Bicarbonate, calcium, carbonate, chloride, hydrogen, hydroxyl, magnesium, potassium, sodium, and sulfate except that: The ion-exchange resin identified in paragraph (a)(12) of this section is used only in accordance with paragraph (b)(1) of this section, the ion-exchange resin identified in paragraph (a)(13) of this section is used only in accordance with paragraph (b)(2) of this section, the resin identified in paragraph (a)(16) of this section is used only in accordance with paragraph (b) (1) or (2) of this section, the ion-exchange resin identified in paragraph (a)(17) of this section is used only in accordance with paragraph (b)(3) of this section, and the ion-exchange resin identified in paragraph (a)(18) of this section is used only in accordance with paragraph (b)(4) of this section.

(1) The ion-exchange resins identified in paragraphs (a) (12) and (16) of this section are used to treat water for use in the manufacture of distilled alcoholic beverages, subject to the following conditions:

(i) The water is subjected to treatment through a mixed bed consisting of one of the resins identified in paragraph (a) (12) or (16) of this section and one of the strongly acidic cation-exchange resins in the hydrogen form identified in paragraphs (a) (1), (2), and (11) of this section; or

(ii) The water is first subjected to one of the resins identified in paragraph (a) (12) or (16) of this section and is subsequently subjected to treatment through a bed of activated carbon or one of the strongly acidic cation-exchange resins in the hydrogen form identified in paragraphs (a) (1), (2), and (11) of this section.

(iii) The temperature of the water passing through the resin beds identified in paragraphs (b)(1) (i) and (ii) of this section is maintained at 30° C or less, and the flow rate of the water passing through the beds is not less than 2 gallons per cubic foot per minute.

(iv) The ion-exchange resins identified in paragraph (a) (12) or (16) of this section are exempted from the requirements of paragraph (c)(4) of this section, but the strongly acidic cation-exchange resins referred to in paragraphs (b)(1) (i) and (ii) of this section used in the process meet the requirements of paragraph (c)(4) of this section, except for the exemption described in paragraph (d) of this section.

(2) The ion-exchange resins identified in paragraphs (a) (13) and (16) of this section are used to treat water and aqueous food only of the types identified under Categories I, II, and VI-B in Table 1 of § 176.170(c) of this chapter: *Provided*, That the temperature of the water or food passing through the resin beds is maintained at 50° C or less and the flow rate of the water or food passing through the beds is not less than 0.5 gallon per cubic foot per minute.

(3) The ion-exchange resin identified in paragraph (a)(17) of this section is used only for industrial application to treat bulk quantities of aqueous food, including potable water, or for treatment of municipal water supplies, subject to the condition that the temperature of the food or water passing through the resin bed is maintained at 25° C or less and the flow rate of the food or water passing through the bed is not less than 2 gallons per cubic foot per minute.

(4) The ion-exchange resin identified in paragraph (a)(18) of this section is used to treat aqueous sugar solutions subject to the condition that the temperature of the sugar solution passing through the resin bed is maintained at 82 °C (179.6 °F) or less and the flow rate of the sugar solution passing through the bed is not less than 46.8 liters per cubic meter (0.35 gallon per cubic foot) of resin bed volume per minute.

(c) To insure safe use of ion-exchange resins, each ion-exchange resin will be:

(1) Subjected to pre-use treatment by the manufacturer and/or the user in accordance with the manufacturer's directions prescribed on the label or labeling accompanying the resins, to guarantee a food-grade purity of ion-exchange resins, in accordance with good manufacturing practice.

(2) Accompanied by label or labeling to include directions for use consistent with the intended functional purpose of the resin.

(3) Used in compliance with the label or labeling required by paragraph (c)(2) of this section.

(4) Found to result in no more than 1 part per million of organic extractives obtained with each of the named solvents, distilled water, 15 percent alcohol, and 5 percent acetic acid when, having been washed and otherwise treated in accordance with the manufacturer's directions for preparing them for use with food, the ion-exchange resin is subjected to the following test: Using a separate ion-exchange column for each solvent, prepare columns using 50 milliliters of the ready to use ion-exchange resin that is to be tested. While maintaining the highest temperature that will be encountered in use pass through these beds at the rate of 350-450 milliliters per hour the three test solvents distilled water, 15 percent (by volume) ethyl alcohol, and 5 percent (by weight) acetic acid. The first liter of effluent from each solvent is discarded, then the next 2 liters are used to determine organic extractives. The 2-liter sample is carefully evaporated to constant weight at 105° C; this is total extractives. This residue is fired in a muffle furnace at 850° C to constant weight; this is ash. Total extractives, minus ash equals the organic extractives. If the organic extractives are greater than 1 part per million of the solvent used, a blank should be run on the solvent and a correction should be made by subtracting the total extractives obtained with the blank from the total extractives obtained in the resin test. The solvents used are to be made as follows:

Distilled water (de-ionized water is distilled).

15 percent ethyl alcohol made by mixing 15 volumes of absolute ethyl alcohol A.C.S. reagent grade, with 85 volumes of distilled de-ionized water.

5 percent acetic acid made by mixing 5 parts by weight of A.C.S. reagent grade glacial acetic acid with 95 parts by weight of distilled de-ionized water.

In addition to the organic extractives limitation prescribed in this paragraph, the ion-exchange resin identified in paragraph (a)(17) of this section, when extracted with each of the named solvents, distilled water, 50 percent alcohol, and 5 percent acetic acid, will be found to result in not more than 7 parts per million of nitrogen extractives (calculated as nitrogen) when the resin in the free-base form is subjected to the following test immediately before each use: Using a separate 1-inch diameter glass ion-exchange column for each solvent, prepare each column using 100 milliliters of ready to use ion-exchange resin that is to be tested. With the bottom outlet closed, fill each ion-exchange column with one of the three solvents at a temperature of 25° C until the solvent level is even with the top of the resin bed. Seal each column at the top and bottom and store in a vertical position at a temperature of 25° C. After 96 hours, open the top of each column, drain the solvent into a collection vessel, and analyze each drained solvent and a solvent blank for nitrogen by a standard micro-Kjeldahl method.

(d) The ion-exchange resins identified in paragraphs (a)(1), (2), (11), and (15) of this section are exempted from the acetic acid extraction requirement of paragraph (c)(4) of this section.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14526, Mar. 15, 1977, as amended at 46 FR 40181, Aug. 7, 1981; 46 FR 57033, Nov. 20, 1981; 47 FR 11838, Mar. 19, 1982; 49 FR 28830, July 17, 1984]

§ 173.40 Molecular sieve resins.

Molecular sieve resins may be safely used in the processing of food under the following prescribed conditions:

(a) The molecular sieve resins consist of purified dextran having an average molecular weight of 40,000, cross-linked with epichlorohydrin in a ratio of 1 part of dextran to 10 parts of epichlorohydrin, to give a stable three dimensional structure. The resins have a pore size of 2.0 to 3.0 milliliters per gram of dry resin (expressed in terms of water regain), and a particle size of 10 to 300 microns.

(b) The molecular sieve resins are thoroughly washed with potable water prior to their first use in contact with food.

(c) Molecular sieve resins are used as the gel filtration media in the final purification of partially delactosed whey. The gel bed shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent microbial build-up on the bed and adulteration of the product.

§ 173.45 Polymaleic acid and its sodium salt.

Polymaleic acid (CAS Reg. No. 26099-09-2) and its sodium salt (CAS Reg. No. 70247-90-4) may be safely used in food in accordance with the following prescribed conditions:

(a) The additives have a minimum average molecular weight of 550-650 and a weight-average molecular weight of 650-850, calculated as the acid. Molecular weight shall be determined by a method entitled "Determination of Molecular Weight Distribution of Poly(Maleic Acid)," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) The additives may be used, individually or together, in the processing of beet sugar juice and liquor or of cane sugar juice and liquor to control mineral scale.

(c) The additives are to be used so that the amount of either or both additives does not exceed 0.4 part per million (calculated as the acid) by weight of the beet or cane sugar juice or liquor process stream.

[51 FR 5315, Feb. 13, 1986]

§ 173.50 Polyvinylpolypyrrolidone.

The food additive polyvinylpolypyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a homopolymer of purified vinylpyrrolidone catalytically produced under conditions producing polymerization and cross-linking such that an insoluble polymer is produced.

(b) The food additive is so processed that when the finished polymer is refluxed for 3 hours with water, 5 percent acetic acid, and 50 percent alcohol, no more than 50 parts per million of extractables is obtained with each solvent.

(c) It is used or intended for use as a clarifying agent in beverages and vinegar, followed by removal with filtration.

§ 173.55 Polyvinylpyrrolidone.

The food additive polyvinylpyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a polymer of purified vinylpyrrolidone catalytically produced, having an average molecular weight of 40,000 and a maximum unsaturation of 1 percent, calculated as the monomer, except that the polyvinylpyrrolidone used in beer is that having an average molecular weight of 360,000 and a maximum unsaturation of 1 percent, calculated as the monomer.

(b) The additive is used or intended for use in foods as follows:

Food	Limitations
Beer	As a clarifying agent, at a residual level not to exceed 10 parts per million.
Flavor concentrates in tablet form	As a tableting adjuvent in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in concentrated liquid form	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in tablet form	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in liquid form	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in tablet form	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vinegar	As a clarifying agent, at a residual level not to exceed 40 parts per million.
Wine	As a clarifying agent, at a residual level not to exceed 60 parts per million.

§ 173.60 Dimethylamine-epichlorohydrin copolymer.

Dimethylamine-epichlorohydrin copolymer (CAS Reg. No. 25988-97-0) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by copolymerization of dimethylamine and epichlorohydrin in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine, and in which the mole ratio of total amine to epichlorohydrin is approximately 1:1.

(b) The additive meets the following specifications:

(1) The nitrogen content of the copolymer is 9.4 to 10.8 weight percent on a dry basis.

(2) A 50-percent-by-weight aqueous solution of the copolymer has a minimum viscosity of 175 centipoises at 25° C as determined by LVT-series Brookfield viscometer using a No. 2 spindle at 60 RPM (or by another equivalent method).

(3) The additive contains not more than 1,000 parts per million of 1,3-dichloro-2-propanol and not more than 10 parts per million epichlorohydrin. The epichlorohydrin and 1,3-dichloro-2-propanol content is determined by an analytical method entitled "The Determination of Epichlorohydrin and 1,3-Dichloro-2-Propanol in Dimethylamine-Epichlorohydrin Copolymer," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) Heavy metals (as Pb), 2 parts per million maximum.

(5) Arsenic (as As), 2 parts per million maximum.

(c) The food additive is used as a decolorizing agent and/or flocculant in the clarification of refinery sugar liquors and juices. It is added only at the defecation/clarification stage of sugar liquor refining at a concentration not to exceed 150 parts per million of copolymer by weight of sugar solids.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the Act, adequate directions to assure use in compliance with paragraph (c) of this section.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[48 FR 37614, Aug. 19, 1983]

§ 173.65 Divinylbenzene copolymer.

Divinylbenzene copolymer may be used for the removal of organic substances from aqueous foods under the following prescribed conditions:

(a) The copolymer is prepared in appropriate physical form and is derived by the polymerization of a grade of divinylbenzene which comprises at least 79 weight-percent divinylbenzene, 15 to 20 weight-percent ethylvinylbenzene, and no more than 4 weight-percent nonpolymerizable impurities.

(b) In accordance with the manufacturer's directions, the copolymer described in paragraph (a) of this section is subjected to pre-use extraction with a water soluble alcohol until the level of divinylbenzene in the extract is less than 50 parts per billion as determined by a method titled, "The Determination of Divinylbenzene in Alcohol Extracts of Amberlite XAD-4," which is incorporated by reference. Copies of this method are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The copolymer is then treated with water according to the manufacturer's recommendation to remove the extraction solvent to guarantee a food-grade purity of the resin at the time of use, in accordance with current good manufacturing practice.

(c) The temperature of the aqueous food stream contacting the polymer is maintained at 79.4 °C (175 °F) or less.

(d) The copolymer may be used in contact with food only of Types I, II, and VI-B (excluding carbonated beverages) described in Table 1 of paragraph (c) of § 176.170 of this chapter.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[50 FR 61, Jan. 2, 1985]

§ 173.70 Chloromethylated aminated styrene-divinylbenzene resin.

Chloromethylated aminated styrene-divinylbenzene copolymer (CAS Reg. No. 60177-39-1) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is an aqueous dispersion of styrene-divinylbenzene copolymers, first chloromethylated then aminated with trimethylamine, having an average particle size of not more than 2.0 microns.

(b) The additive shall contain no more than 3.0 percent nonvolatile, soluble extractives when tested as follows: One hundred grams of the additive is centrifuged at 17,000 r/min for 2 hours. The resulting clear supernatant is removed from the compacted solids and concentrated to approximately 10 grams on a steam bath. The 10-gram sample is again centrifuged at 17,000 r/min for 2 hours to remove any residual insoluble material. The supernatant from the second centrifugation is then removed from any compacted solids and dried to constant residual weight using a steam bath. The percent nonvolatile solubles is obtained by dividing the weight of the dried residue by the weight of the solids in the original resin dispersion.

(c) The additive is used as a decolorizing and clarification agent for treatment of refinery sugar liquors and juices at levels not to exceed 500 parts of additive solids per million parts of sugar solids.

[50 FR 29209, July 18, 1985]

§ 173.75 Sorbitan monooleate.

Sorbitan monooleate may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by the esterification of sorbitol with commercial oleic acid.

(b) It meets the following specifications:

(1) Saponification number, 145-160.

(2) Hydroxyl number, 193-210.

(c) The additive is used or intended for use as follows:

(1) As an emulsifier in polymer dispersions that are used in the clarification of cane or beet sugar juice or liquor in an amount not to exceed 7.5 percent by weight in the final polymer dispersion.

(2) The additive is used in an amount not to exceed 0.70 part per million in sugar juice and 1.4 parts per million in sugar liquor.

[51 FR 11720, Apr. 7, 1986]

Subpart B—Enzyme Preparations and Microorganisms

§ 173.110 Amyloglucosidase derived from *Rhizopus niveus.*

Amyloglucosidase enzyme product, consisting of enzyme derived from *Rhizopus niveus,* and diatomaceous silica as a carrier, may be safely used in food in accordance with the following conditions:

(a) *Rhizopus niveus* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *niveus.*

(b) The strain of *Rhizopus niveus* is nonpathogenic and nontoxic in man or other animals.

(c) The enzyme is produced by a process which completely removes the organism *Rhizopus niveus* from the amyloglucosidase.

(d) The additive is used or intended for use for degrading gelatinized starch into constituent sugars, in the production of distilled spirits and vinegar.

(e) The additive is used at a level not to exceed 0.1 percent by weight of the gelatinized starch.

§ 173.120 Carbohydrase and cellulase derived from *Aspergillus niger.*

Carbohydrase and cellulase enzyme preparation derived from *Aspergillus niger* may be safely used in food in accordance with the following prescribed conditions:

(a) *Aspergillus niger* is classified as follows: Class, Deuteromycetes; order, Moniliales; family, Moniliaceae; genus, *Aspergillus;* species, *niger.*

(b) The strain of *Aspergillus niger* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the organism *Aspergillus niger* from the carbohydrase and cellulase enzyme product.

(d) The additive is used or intended for use as follows:

(1) For removal of visceral mass (bellies) in clam processing.

(2) As an aid in the removal of the shell from the edible tissue in shrimp processing.

(e) The additive is used in an amount not in excess of the minimum required to produce its intended effect.

§ 173.130 Carbohydrase derived from *Rhizopus oryzae.*

Carbohydrase from *Rhizopus oryzae* may be safely used in the production of dextrose from starch in accordance with the following prescribed conditions:

(a) *Rhizopus oryzae* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *Rhizopus oryzae.*

(b) The strain of *Rhizopus oryzae* is nonpathogenic and nontoxic.

(c) The carbohydrase is produced under controlled conditions to maintain nonpathogenicity and nontoxicity, including the absence of aflatoxin.

(d) The carbohydrase is produced by a process which completely removes the organism *Rhizopus oryzae* from the carbohydrase product.

(e) The carbohydrase is maintained under refrigeration from production to use and is labeled to include the necessity of refrigerated storage.

§ 173.135 Catalase derived from *Micrococcus lysodeikticus.*

Bacterial catalase derived from *Micrococcus lysodeikticus* by a pure culture fermentation process may be safely used in destroying and removing hydrogen peroxide used in the manufacture of cheese, in accordance with the following conditions.

(a) The organism *Micrococcus lysodeikticus* from which the bacterial catalase is to be derived is demonstrated to be nontoxic and nonpathogenic.

(b) The organism *Micrococcus lysodeikticus* is removed from the bacterial catalase prior to use of the bacterial catalase.

(c) The bacterial catalase is used in an amount not in excess of the minimum required to produce its intended effect.

§173.140 Esterase-lipase derived from Mucor miehei.

Esterase-lipase enzyme, consisting of enzyme derived from *Mucor miehei* var. *Cooney et Emerson* by a pure culture fermentation process, with maltodextrin or sweet whey as a carrier, may be safely used in food in accordance with the following conditions:

(a) *Mucor miehei* var. *Cooney et Emerson* is classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *miehei;* variety *Cooney et Emerson.*

(b) The strain of *Mucor miehei* var. *Cooney et Emerson* is nonpathogenic and nontoxic in man or other animals.

(c) The enzyme is produced by a process which completely removes the organism *Mucor miehei* var. *Cooney et Emerson* from the esterase-lipase.

(d) The enzyme is used as a flavor enhancer as defined in § 170.3(o)(12).

(e) The enzyme is used at levels not to exceed current good manufacturing practice in the following food categories: cheeses as defined in § 170.3(n)(5) of this chapter; fat and oils as defined in § 170.(3)(n)(12) of this chapter; and milk products as defined in § 170.(3)(n)(31) of this chapter. Use of this food ingredient is limited to nonstandarized foods and those foods for which the relevant standards of identity permit such use.

(f) The enzyme is used in the minimum amount required to produce its limited technical effect.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[47 FR 28090, June 29, 1982; 48 FR 2748, Jan. 21, 1983]

§ 173.145 Alpha-Galactosidase derived from *Mortierella vinaceae* var. *raffinoseutilizer.*

The food additive alpha-galactosidase and parent mycelial microorganism *Mortierella vinaceae* var. *raffinoseutilizer* may be safely used in food in accordance with the following conditions:

(a) The food additive is the enzyme alpha-galactosidase and the mycelia of the microorganism *Mortierella vinaceae* var. *raffinoseutilizer* which produces the enzyme.

(b) The nonpathogenic microorganism matches American Type Culture Collection (ATCC) No. 20034,[1] and is classified as follows:

Class: Phycomycetes.
Order: Mucorales.
Family: Mortierellaceae.
Genus: *Mortierella.*
Species: *vinaceae.*
Variety: *raffinoseutilizer.*

(c) The additive is used or intended for use in the production of sugar (sucrose) from sugar beets by addition as mycelial pellets to the molasses to increase the yield of sucrose, followed by removal of the spent mycelial pellets by filtration.

(d) The enzyme removal is such that there are no enzyme or mycelial residues remaining in the finished sucrose.

§ 173.150 Milk-clotting enzymes, microbial.

Milk-clotting enzyme produced by pure-culture fermentation process may be safely used in the production of cheese in accordance with the following prescribed conditions:

(a) Milk-clotting enzyme is derived from one of the following organisms by a pure-culture fermentation process:

(1) *Endothia parasitica* classified as follows: Class, Ascomycetes; order, Sphaeriales; family, Diaporthacesae; genus, *Endothia;* species, *parasitica.*

(2) *Bacillus cereus* classified as follows: Class, Schizomycetes; order, Eubacteriales; family, Bacillaceae, genus,

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[1] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 30852.

Bacillus; species, *cereus* (Frankland and Frankland).

(3) *Mucor pusillus* Lindt classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *pusillus;* variety, *Lindt.*

(4) *Mucor miehei* Cooney et Emerson classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *miehei;* variety, *Cooney et Emerson.*

(b) The strains of organism identified in paragraph (a) of this section are nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the generating organism from the milk-clotting enzyme product.

(d) The additive is used in an amount not in excess of the minimum required to produce its intended effect in the production of those cheeses for which it is permitted by standards of identity established pursuant to section 401 of the act.

[42 FR 14526, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 173.160 *Candida guilliermondii.*

The food additive *Candida guilliermondii* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the viable organism *Candida guilliermondii* and its concomitant metabolites produced during the fermentation process.

(b)(1) The nonpathogenic and nontoxicogenic organism descending from strain, American Type Culture Collection (ATCC) No. 20474,[1] is classified as follows:

Class: Deuteromycetes.
Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida.*
Species: *guilliermondii.*
Variety: *guilliermondii.*

(2) The toxonomic characteristics of the reference culture strain ATCC No. 20474 agree in the essentials with the standard description for *Candida guilliermondii* variety *guilliermondii* listed in "The Yeasts—A Toxonomic Study;" 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c)(1) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid using an acceptable aqueous carbohydrate substrate.

(2) The organism *Candida quilliermondii* is made nonviable and is completely removed from the citric acid during the recovery and purification process.

(d) The additive is so used that the citric acid produced conforms to the specifications of the "Food Chemicals Codex," 3d Ed. (1981), under "Citric acid," pp. 86-87, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register., 1100 L St. NW., Washington, DC 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14526, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984]

§ 173.165 *Candida lipolytica.*

The food additive *Candida lipolytica* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the organism *Candida lipolytica* and its concimitant metabolites produced during the fermentation process.

(b)(1) The nonpathogenic organism is classified as follows:

Class: Deuteromycetes.

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[1] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 30852.

Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida*.
Species: *lipolytica*.

(2) The taxonomic characteristics of the culture agree in essential with the standard description for *Candida lipolytica* variety *lipolytica* listed in "The Yeasts—A Toxonomic Study," 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid from purified normal alkanes.

(d) The additive is so used that the citric acid produced conforms to the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Wasington, DC 20408. The additive meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in this paragraph:

Ultraviolet absorbance per centimeter path length	Maximum
280 to 289 millimicrons	0.25
290 to 299 millimicrons	0.20
300 to 359 millimicrons	0.13
360 to 400 millimicrons	0.03

ANALYTICAL PROCEDURE FOR CITRIC ACID

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of citric acid samples in handling is essential to assure absence of any extraneous material arising from inadequate packaging. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

1. Aluminum foil, oil free.
2. Separatory funnels, 500-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.
3. Chromatographic tubes: (a) 80-millimeter ID x 900-millimeter length equipped with tetrafluoroethylene polymer stopcock and course fritted disk; (b) 18-millimeter ID x 300-millimeter length equipped with tetrafluoroethylene polymer stopcock.
4. Rotary vacuum evaporator, Buchi or equivalent.
5. Spectrophotometer—Spectral range 250-400 nanometers with spectral slit width of 2 nanometers or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Wavelength repeatability, ±0.2 nanometer.

Wavelength accuracy, ±1.0 nanometer.

The spectrophotometer is equipped with matched 1 centimeter path length quartz microcuvettes with 0.5-milliliter volume capacity.

6. Vacuum oven, minimum inside dimensions: 200 mm × 200 mm × 300 mm deep.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The methyl alcohol, isooctane, benzene, hexane and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

The specified quantity of solvent is added to a 250-milliliter round bottom flask containing 0.5 milliliter of purified *n*-hexadecane and evaporated on the rotary evaporator at 45° C to constant volume. Six milliliters of purified isooctane are added to this residue and evaporated under the same conditions as above for 5 minutes. Determine the absorbance of the residue compared to purified *n*-hexadecane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.03 per centimeter path length between 280 and 299 nanometers and 0.01 per centimeter path length between 300 and 400 nanometers.

Methyl alcohol, A.C.S. reagent grade. Use 100 milliliters for the test described in the preceding paragraph. If necessary, methyl alcohol may be purified by distillation through a Virgreaux column discarding the first and last ten percent of the distillate or otherwise.

Benzene, spectrograde (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 80 milliliters for the test. If necessary, benzene may be purified by distillation or otherwise.

Isooctane (2,2,4-trimethylpentane). Use 100 milliliters for the test. If necessary, isooctane may be purified by passage through a column of activated silica gel, distillation or otherwise.

Hexane, spectrograde (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 100 milliliters for the test. If necessary, hexane may be purified by distillation or otherwise.

1,2-Dichloroethane, spectrograde (Matheson, Coleman and Bell, East Rutherford, N.J., or equivalent). Use 100 milliliters for the test. If necessary, 1,2-dichloroethane may be purified by distillation or otherwise.

ELUTING MIXTURES

1. *10 percent 1,2-dichloroethane in hexane.* Prepare by mixing the purified solvents in the volume ratio of 1 part of 1,2-dichloroethane to 9 parts of hexane.

2. *40 percent benzene in hexane.* Prepare by mixing the purified solvents in the volume ratio of 4 parts of benzene to 6 parts of hexane.

n-Hexadecane, 99 percent olefin-free. Determine the absorbance compared to isooctane as reference. The absorbance per centimeter path length shall not exceed 0.00 in the range of 280-400 nanometers. If necessary, *n*-hexadecane may be purified by percolation through activated silica gel, distillation or otherwise.

Silica gel, 28-200 mesh (Grade 12, Davison Chemical Co., Baltimore, MD, or equivalent). Activate as follows: Slurry 900 grams of silica gel reagent with 2 liters of purified water in a 3-liter beaker. Cool the mixture and pour into a 80 × 900 chromatographic column with coarse fritted disc. Drain the water, wash with an additional 6 liters of purified water and wash with 3,600 milliliters of purified methyl alcohol at a relatively slow rate. Drain all of the solvents and transfer the silica gel to an aluminum foil-lined drying dish. Place foil over the top of the dish. Activate in a vacuum oven at low vacuum (approximately 750 millimeters Mercury or 27 inches of Mercury below atmospheric pressure) at 173° to 177° C for at least 20 hours. Cool under vacuum and store in an amber bottle.

Sodium sulfate, anhydrous, A.C.S. reagent grade. This reagent should be washed with purified isooctane. Check the purity of this reagent as described in § 172.886 of this chapter.

Water, purified. All water used must meet the specifications of the following test:

Extract 600 milliliters of water with 50 milliliters of purified isooctane. Add 1 milliliter of purified *n*-hexadecane to the isooctane extract and evaporate the resulting solution to 1 milliliter. The absorbance of this residue shall not exceed 0.02 per centimeter path length between 300-400 nanometers and 0.03 per centimeter path length between 280-299 nanometers. If necessary, water may be purified by distillation, extraction with purified organic solvents, treatment with an absorbent (e.g., activated carbon) followed by filtration of the absorbent or otherwise.

PROCEDURE

Separate portions of 200 milliliters of purified water are taken through the procedure for use as control blanks. Each citric acid sample is processed as follows: Weigh 200 grams of anhydrous citric acid into a 500 milliliter flask and dissolve in 200 milliliters of pure water. Heat the solution to 60° C and transfer to a 500 milliliter separatory funnel. Rinse the flask with 50 milliliters of isooctane and add the isooctane to the separatory funnel. Gently shake the mixture 90 times (caution: vigorous shaking will cause emulsions) with periodic release of the pressure caused by shaking.

Allow the phases to separate for at least 5 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with a second aliquot of 50 milliliters of isooctane. After separation of the layers, draw off and discard the water layer. Combine both isooctane extracts in the funnel containing the first extract. Rinse the funnel which contained the second extract with 10 milliliters of isooctane and add this portion to the combined isooctane extract.

A chromatographic column containing 5.5 grams of silica gel and 3 grams of anhydrous sodium sulfate is prepared for each citric acid sample as follows: Fit 18 × 300 column with a small glass wool plug. Rinse the inside of the column with 10 milliliters of purified isooctane. Drain the isooctane from the column. Pour 5.5 grams of activated silica gel into the column. Tap the column approximately 20 times on a semisoft, clean surface to settle the silica gel. Carefully pour 3 grams of anhydrous sodium sulfate onto the top of the silica gel in the column.

Carefully drain the isooctane extract of the citric acid solution into the column in a series of additions while the isooctane is draining from the column at an elution rate of approximately 3 milliliters per minute. Rinse the separatory funnel with 10 milliliters of isooctane after the last portion of the extract has been applied to the column and add this rinse to the column. After all of the extract has been applied to the column and the solvent layer reaches the top of the sulfate bed, rinse the column with 25 milliliters of isooctane followed by 10 milliliters of a 10-percent dichloroethane in hexane solution. For each rinse solution, drain the column until the solvent layer reaches the top of the sodium sulfate bed. Discard the rinse solvents. Place a 250-milliliter round bottom flask containing 0.5 milliliter of purified *n*-hexadecane under the column. Elute the polynuclear aromatic hydrocarbons from the column with 30 milliliters of 40-percent benzene in hexane solution. Drain the eluate until the 40-percent benzene in the hexane solvent reaches the top of the sodium sulfate bed.

Evaporate the 40-percent benzene in hexane eluate on the rotary vacuum evaporator at 45° C until only the *n*-hexadecane residue of 0.5 milliliter remains. Treat the *n*-hexadecane residue twice with the following wash step: Add 6 milliliters of purified isooctane and remove the solvents by vacuum evaporation at 45° C to constant volume, i.e., 0.5 milliliter. Cool the *n*-hexadecane residue and transfer the solution to an 0.5-milliliter microcuvette. Determine the absorbance of this solution compared to purified *n*-hexadecane as reference. Correct the absorbance values for any absorbance derived from the control reagent blank. If the corrected absorbance does not exceed the limits prescribed, the samples meet the ultraviolet absorbance specifications.

The reagent blank is prepared by using 200 milliliters of purified water in place of the citric acid solution and carrying the water sample through the procedure. The typical control reagent blank should not exceed 0.03 absorbance per centimeter path length between 280 and 299 nanometers, 0.02 absorbance per centimeter path length between 300 and 359 nanometers, and 0.01 absorbance per centimeter path length between 360 and 400 nanometers.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984]

Subpart C—Solvents, Lubricants, Release Agents and Related Substances

§ 173.210 Acetone.

A tolerance of 30 parts per million is established for acetone in spice oleoresins when present therein as a residue from the extraction of spice.

§ 173.220 1,3-Butylene glycol.

1,3-Butylene glycol (1,3-butanediol) may be safely used in food in accordance with the following prescribed conditions:

(a) The substance meets the following specifications:

(1) 1,3-Butylene glycol content: Not less than 99 percent.

(2) Specific gravity at 20/20° C: 1.004 to 1.006.

(3) Distillation range: 200°-215° C.

(b) It is used in the minimum amount required to perform its intended effect.

(c) It is used as a solvent for natural and synthetic flavoring substances except where standards of identity issued under section 401 of the act preclude such use.

§ 173.228 Ethyl acetate.

Ethyl acetate (CAS Reg. No. 141-78-6) may be safely used in food in accordance with the following conditions:

(a) The additive meets the specifications of the Food Chemicals Codex,[1] (Ethyl Acetate; p. 372, 3d Ed., 1981), which are incorporated by reference.

(b) The additive is used in accordance with current good manufacturing practice as a solvent in the decaffeination of coffee and tea.

(Secs. 201(s) 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[47 FR 146, Jan. 5, 1982, as amended at 49 FR 28548, July 13, 1984]

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[1] Copies may be obtained from: National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418 or examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

§ 173.230 Ethylene dichloride.

A tolerance of 30 parts per million is established for ethylene dichloride in spice oleoresins when present therein as a residue from the extraction of spice; *Provided, however*, That if residues of other chlorinated solvents are also present the total of all residues of such solvents shall not exceed 30 parts per million.

§ 173.240 Isopropyl alcohol.

Isopropyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In lemon oil as a residue in production of the oil, at a level not to exceed 6 parts per million.

(c) In hops extract as a residue from the extraction of hops at a level not to exceed 2.0 percent by weight: *Provided*, That,

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of the isopropyl alcohol and provides for the use of the hops extract only as prescribed by paragraph (c)(1) of this section.

§ 173.250 Methyl alcohol residues.

Methyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; *Provided*, That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of methyl alcohol and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section.

§ 173.255 Methylene chloride.

Methylene chloride may be present in food under the following conditions:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 30 parts per million; *Provided*, That, if residues of other chlorinated solvents are also present, the total of all residues of such solvents shall not exceed 30 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent, *Provided*, That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract identifies the presence of the methylene chloride and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section.

(c) In coffee as a residue from its use as a solvent in the extraction of caffeine from green coffee beans, at a level not to exceed 10 parts per million (0.001 percent) in decaffeinated roasted coffee and in decaffeinated soluble coffee extract (instant coffee).

§ 173.270 Hexane.

Hexane may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 25 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; *Provided*, That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of the hexane and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section.

§ 173.275 Hydrogenated sperm oil.

The food additive hydrogenated sperm oil may be safely used in accordance with the following prescribed conditions:

(a) The sperm oil is derived from rendering the fatty tissue of the sperm whale or is prepared by synthesis of fatty acids and fatty alcohols derived from the sperm whale. The sperm oil obtained by rendering is refined. The oil is hydrogenated.

(b) It is used alone or as a component of a release agent or lubricant in bakery pans.

(c) The amount used does not exceed that reasonably required to accomplish the intended lubricating effect.

§ 173.280 Solvent extraction process for citric acid.

A solvent extraction process for recovery of citric acid from conventional *Aspergillus niger* fermentation liquor may be safely used to produce food-grade citric acid in accordance with the following conditions:

(a) The solvent used in the process consists of a mixture of *n*-octyl alcohol meeting the requirements of § 172.864 of this chapter, synthetic isoparaffinic petroleum hydrocarbons meeting the requirements of § 172.882 of this chapter, and tridodecyl amine.

(b) The component substances are used solely as a solvent mixture and in a manner that does not result in formation of products not present in conventionally produced citric acid.

(c) The citric acid so produced meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and the polynuclear aromatic hydrocarbon specifications of § 173.165.

(d) Residues of *n*-octyl alcohol and synthetic isoparaffinic petroleum hydrocarbons are removed in accordance with good manufacturing practice. Current good manufacturing practice results in residues not exceeding 16 parts per million (ppm) *n*-octyl alcohol and 0.47 ppm synthetic isoparaffinic petroleum hydrocarbons in citric acid.

(e) Tridodecyl amine may be present as a residue in citric acid at a level not to exceed 100 parts per billion.

(Secs. 201(s), 409, 710(a), 52 Stat. 1055, 72 Stat. 1784-1788, as amended (21 U.S.C. 321(s), 348, 371(a)); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10106, Mar. 19, 1984]

§ 173.290 Trichloroethylene.

Tolerances are established for residues of trichloroethylene resulting from its use as a solvent in the manufacture of foods as follows:

Decaffeinated ground coffee	25 parts per million.
Decaffeinated soluble (instant) coffee extract.	10 parts per million.
Spice oleoresins	30 parts per million (provided that if residues of other chlorinated solvents are also present, the total of all residues of such solvents in spice oleoresins shall not exceed 30 parts per million).

Subpart D—Specific Usage Additives

§ 173.310 Boiler water additives.

Boiler water additives may be safely used in the preparation of steam that will contact food, under the following conditions:

(a) The amount of additive is not in excess of that required for its functional purpose, and the amount of steam in contact with food does not exceed that required to produce the intended effect in or on the food.

(b) The compounds are prepared from substances identified in paragraphs (c) and (d) of this section, and are subject to the limitations, if any, prescribed:

(c) List of substances:

Substances	Limitations
Acrylamide-sodium acrylate resin	Contains not more than 0.05 percent by weight of acrylamide monomer.
Ammonium alginate	
Cobalt sulfate (as catalyst)	
1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) and its sodium and potassium salts.	
Lignosulfonic acid	

Substances	Limitations
Monobutyl ethers of polyethylene-polypropylene glycol produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol.	Minimum mol. wt. 1,500.
Poly(acrylic acid-*co*-hypophosphite), sodium salt (CAS Reg. No. 71050-62-9), produced from a 4:1 mixture by weight of acrylic acid and sodium hypophosphite.	Total not to exceed 1.5 parts per million in boiler feed water. Copolymer contains not more than 0.5 percent by weight of acrylic acid monomer (dry weight basis).
Polyethylene glycol	As defined in § 172.820 of this chapter.
Polymaleic acid [CAS Reg. No. 26099-09-2], and/or its sodium salt. [CAS Reg. No. 30915-61-8].	Total not to exceed 1 part per million in boiler feed water (calculated as the acid).
Polyoxypropylene glycol	Minimum mol. wt. 1,000.
Potassium carbonate	
Potassium tripolyphosphate	
Sodium acetate	
Sodium alginate	
Sodium aluminate	
Sodium carbonate	
Sodium carboxy-methylcellulose	Contains not less than 95 percent sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25° C; by method prescribed in the "Food Chemicals Codex," 3d Ed. (1981), pp. 280-282, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.
Sodium glucoheptonate	Less than 1 part per million cyanide in the sodium glucoheptonate.
Sodium hexametaphosphate	
Sodium humate	
Sodium hydroxide	
Sodium lignosulfonate	
Sodium metabisulfite	
Sodium metasilicate	
Sodium nitrate	
Sodium phosphate (mono-, di-, tri-)	
Sodium polyacrylate	
Sodium polymethacrylate	
Sodium silicate	
Sodium sulfate	
Sodium sulfite (neutral or alkaline)	
Sodium tripolyphosphate	
Tannin (including quebracho extract)	
Tetrasodium EDTA	
Tetrasodium pyrophosphate	

(d) Substances used alone or in combination with substances in paragraph (c) of this section:

Substances	Limitations
Cyclohexylamine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Diethylaminoethanol	Not to exceed 15 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Hydrazine	Zero in steam.
Morpholine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Octadecylamine	Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Trisodium nitrilotriacetate	Not to exceed 5 parts per million in boiler feedwater; not to be used where steam will be in contact with milk and milk products.

(e) To assure safe use of the additive, in addition to the other information required by the Act, the label or labeling shall bear:

(1) The common or chemical name or names of the additive or additives.

(2) Adequate directions for use to assure compliance with all the provisions of this section.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14526, Mar. 15, 1977, as amended at 45 FR 73922, Nov. 7, 1980; 45 FR 85726, Dec. 30, 1980; 48 FR 7439, Feb. 22, 1983; 49 FR 5748, Feb. 15, 1984; 49 FR 10106, Mar. 19, 1984; 50 FR 49536, Dec. 3, 1985]

§ 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

Chemicals may be safely used to wash or to assist in the lye peeling of fruits and vegetables in accordance with the following conditions:

(a) The chemicals consist of one or more of the following:

(1) Substances generally recognized as safe in food or covered by prior sanctions for use in washing fruits and vegetables.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
A mixture of alkylene oxide adducts of alkyl alcohols and phosphate esters of alkylene oxide adducts of alkyl alcohols consisting of: α-alkyl (C_{12}-C_{18})-*omega*-hydroxy-poly (oxyethylene) (7.5–8.5 moles)/poly (oxypropylene) block copolymer having an average molecular weight of 810; α-alkyl (C_{12}-C_{18})-*omega*-hydroxy-poly (oxyethylene) (3.3-3.7 moles) polymer having an average molecular weight of 380, and subsequently esterified with 1.25 moles phosphoric anhydride; and α-alkyl (C_{10}-C_{12})-*omega*-hydroxypoly (oxyethylene) (11.9-12.9 moles)/poly (oxypropylene) copolymer, having an average molecular weight of 810, and subsequently esterified with 1.25 moles phosphoric anhydride.	May be used at a level not to exceed 0.2 percent in lye-peeling solution to assist in the lye peeling of fruit and vegetables.
Aliphatic acid mixture consisting of valeric, caproic, enanthic, caprylic, and pelargonic acids.	May be used at a level not to exceed 1 percent in lye peeling solution to assist in the lye peeling of fruits and vegetables.
Polyacrylamide	Not to exceed 10 p.p.m. in wash water. Contains not more than 0.2 percent acrylamide monomer.
Potassium bromide	Not to exceed 0.2 percent in wash water. May be used in washing or to assist in the lye peeling of fruits and vegetables.
Sodium *n*-alkylbenzene-sulfonate (alkyl group predominantly C_{12} and C_{13} and not less than 95 percent C_{10} to C_{14}).	Do.
Sodium dodecylbenzene-sulfonate (alkyl group predominantly C_{12} and not less than 95% C_{10} to C_{14}).	Do.
Sodium 2 ethyl-hexyl sulfate	
Sodium hypochlorite	
Sodium mono- and di-methyl naphthalene sulfonates (mol. wt. 245-260).	Not to exceed 0.2 percent in wash water. May be used in the washing or to assist in the lye peeling of fruits and vegetables.

(3) Substances identified in this paragraph (a)(3) for use in flume water for washing sugar beets prior to the slicing operation and subject to the limitations as are provided for the level of the substances in the flume water:

Substance	Limitations
α-Alkyl-*omega*-hydroxypoly-(oxyethylene) produced by condensation of 1 mole of C_{11}-C_{15} straight chain randomly substituted secondary alcohols with an average of 9 moles of ethylene oxide.	Not to exceed 3 ppm.
Linear undecylbenzenesulfonic acid.	Do.

Substance	Limitations
Dialkanolamide produced by condensing 1 mole of methyl laurate with 1.05 moles of diethanolamine.	Not to exceed 2 ppm.
Triethanolamine	Do.
Ethylene glycol monobutyl ether	Not to exceed 1 ppm.
Oleic acid conforming with § 172.860 of this chapter.	Do.
Tetrapotassium pyrophosphate	Not to exceed 0.3 ppm.
Monoethanolamine	Do.
Ethylene dichloride	Not to exceed 0.2 ppm.
Tetrasodium ethylenediaminetetraacetate.	Not to exceed 0.1 ppm.

(b) The chemicals are used in amounts not in excess of the minimum required to accomplish their intended effect.

(c) The use of the chemicals is followed by rinsing with potable water to remove, to the extent possible, residues of the chemicals.

(d) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive or a statement of its composition.

(2) The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of this section.

[42 FR 14526, Mar. 15, 1977, as amended at 42 FR 29856, June 10, 1977; 42 FR 32229, June 24, 1977. 43 FR 54926, Nov. 24, 1978]

§ 173.320 Chemicals for controlling microorganisms in cane-sugar and beet-sugar mills.

Agents for controlling microorganisms in cane-sugar and beet-sugar mills may be safely used in accordance with the following conditions:

(a) They are used in the control of microorganisms in cane-sugar and/or beet-sugar mills as specified in paragraph (b) of this section.

(b) They are applied to the sugar mill grinding, crusher, and/or diffuser systems in one of the combinations listed in paragraph (b) (1), (2), (3), or (5) of this section or as a single agent listed in paragraph (b)(4) of this section. Quantities of the individual additives in parts per million are expressed in terms of the weight of the raw cane or raw beets.

(1) Combination for cane-sugar mills:

	Parts per million
Disodium cyanodithioimidocarbonate	2.5
Ethylenediamine	1.0
Potassium *N*-methyldithiocarbamate	3.5

(2) Combination for cane-sugar mills:

	Parts per million
Disodium ethylenebisdithiocarbamate	3.0
Sodium dimethyldithiocarbamate	3.0

(3) Combinations for cane-sugar mills and beet-sugar mills:

	Parts per million
(i) Disodium ethylenebisdithiocarbamate	3.0
Ethylenediamine	2.0
Sodium dimethyldithiocarbamate	3.0
(ii) Disodium cyanodithioimidocarbonate	2.9
Potassium *N*-methyldithiocarbamate	4.1

(4) Single additive for cane-sugar mills and beet-sugar mills.

	Parts per million
2,2-Dibromo-3-nitrilopropionamide (CAS Reg. No. 10222-01-2). *Limitations*: By-product molasses, bagasse, and pulp containing residues of 2,2-dibromo-3-nitrilopropionamide are not authorized for use in animal feed.	Not more than 10.0 and not less than 2.0.

(5) Combination for cane-sugar mills:

	Parts per million
n-Dodecyl dimethyl benzyl ammonium chloride	0.05 ± 0.005
n-Dodecyl dimethyl ethylbenzyl ammonium chloride	0.68 ± 0.068
n-Hexadecyl dimethyl benzyl ammonium chloride	0.30 ± 0.030
n-Octadecyl dimethyl benzyl ammonium chloride	0.05 ± 0.005
n-Tetradecyl dimethyl benzyl ammonium chloride	0.60 ± 0.060

	Parts per million
n-Tetradecyl dimethyl ethylbenzyl ammonium chloride	0.32±0.032

Limitations. Byproduct molasses, bagasse, and pulp containing residues of these quaternary ammonium salts are not authorized for use in animal feed.

(c) To assure safe use of the additives, their label and labeling shall conform to that registered with the Environmental Protection Agency.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14526, Mar. 15, 1977, as amended at 47 FR 35756, Aug. 17, 1982; 50 FR 3891, Jan. 29, 1985]

§ 173.322 Chemicals used in delinting cottonseed.

Chemicals may be safely used to assist in the delinting of cottonseed in accordance with the following conditions:

(a) The chemicals consist of one or more of the following:

(1) Substances generally recognized as safe for direct addition to food.

(2) Substances identified in this paragraph and subject to such limitations as are provided:

Substances	Limitations
alpha-Alkyl-omega-hydroxypoly-(oxyethylene) produced by condensation of a linear primary alcohol containing an average chain length of 10 carbons with poly(oxyethylene) having an average of 5 ethylene oxide units.	May be used at an application rate not to exceed 0.3 percent by weight of cottonseeds to enhance delinting of cottonseeds intended for the production of cottonseed oil. Byproducts including lint, hulls, and meal may be used in animal feed.
An alkanomide produced by condensation of coconut oil fatty acids and diethanolamine, CAS Reg. No. 068603-42-9.	May be used at an application rate not to exceed 0.2 percent by weight of cottonseeds to enhance delinting of cottonseeds intended for the production of cottonseed oil. Byproducts including lint, hulls, and meal may be used in animal feed.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[47 FR 8346, Feb. 26, 1982]

§ 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200° C; viscosity 300 to 1,050 centistokes at 25° C; refractive index 1.400–1.404 at 25° C).	10 parts per million in food, or at such level in a concentrated food that when prepared as directed on the labels, the food in its ready-for-consumption state will have not more than 10 parts per million except as follows: Zero in milk; 110 parts per million in dry gelatin dessert mixes labeled for use whereby no more than 16 parts per million is present in the ready-to-serve dessert; 250 parts per million in salt labeled for cooking purposes, whereby no more than 10 parts per million is present in the cooked food.
Formaldehyde	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount not exceeding 1.0 percent of the dimethylpolysiloxane content.
α-Hydro-omega-hydroxy-poly (oxyethylene)/poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer (CAS Reg. No. 9003-11-6) as defined in § 172.808(a)(3) of this chapter.	For use as prescribed in § 172.808(b)(3) of this chapter.
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane in an amount reasonably required to accomplish the intended effect.
Polyethylene glycol	As defined in § 172.820 of this chapter.
Polyoxyethylene 40 monostearate	As defined in U.S.P. XVI.
Polysorbate 60	As defined in § 172.836 of this chapter.
Polysorbate 65	As defined in § 172.838 of this chapter.
Propylene glycol alginate	As defined in § 172.858 of this chapter.
Silicon dioxide	As defined in § 172.480 of this chapter.

Substances	Limitations
Sorbitan monostearate	As defined in § 172.842 of this chapter.
White mineral oil: Conforming with § 172.878 of this chapter	As a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008 percent of the wash water.

(3) Substances listed in this paragraph (a)(3), provided they are components of defoaming agents limited to use in processing beet sugar and yeast, and subject to any limitations imposed:

Substances	Limitations
Aluminum stearate	As defined in § 172.863 of this chapter.
Butyl stearate	
BHA	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
BHT	Do.
Calcium stearate	As defined in § 172.863 of this chapter.
Fatty acids	As defined in § 172.860 of this chapter.
Formaldehyde	As a preservative.
Hydroxylated lecithin	As defined in § 172.814 of this chapter.
Isopropyl alcohol	
Magnesium stearate	As defined in § 172.863 of this chapter.
Mineral oil: Conforming with § 172.878 of this chapter	Not more than 150 p.p.m. in yeast, measured as hydrocarbons.
Odorless light petroleum hydrocarbons: Conforming with § 172.884 of this chapter.	
Petrolatum: Conforming with § 172.880 of this chapter	
Petroleum wax: Conforming with § 172.886 of this chapter	
Petroleum wax, synthetic	
Polyethylene glycol (400)dioleate: Conforming with § 172.820(a)(2) of this chapter and providing the oleic acid used in the production of this substance complies with § 172.860 or § 172.862 of this chapter.	As an emulsifier not to exceed 10 percent by weight of defoamer formulation.
Synthetic isoparaffinic petroleum hydrocarbons: Conforming with § 172.882 of this chapter.	
Oleic acid derived from tall oil fatty acids	Complying with § 172.862 of this chapter.
Oxystearin	As defined in § 172.818 of this chapter.
Polyoxyethylene (600) dioleate	
Polyoxyethylene (600) monoricinoleate	
Polypropylene glycol	Molecular weight range, 1,200–2,500.
Polysorbate 60	As defined in § 172.840 of this chapter.
Potassium stearate	As defined in § 172.863 of this chapter.
Propylene glycol mono- and diesters of fats and fatty acids	As defined in § 172.856 of this chapter.
Soybean oil fatty acids, hydroxylated	
Tallow, hydrogenated, oxidized or sulfated	
Tallow alcohol, hydrogenated	

(4) The substance listed in this paragraph (a)(4), provided it is a component of defoaming agents limited to use in processing beet sugar only, and subject to the limitations imposed:

Substance	Limitations
n-Butoxypolyoxyethyl-ene polyoxypropylene glycol.	Molecular weight range, 3,900–4,100 (hydroxyl determination).

(b) They are added in an amount not in excess of that reasonably required to inhibit foaming.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 2872, Jan. 20, 1978; 46 FR 30493, June 9, 1981; 46 FR 57476, Nov. 24, 1981]

§ 173.345 Chloropentafluoroethane.

The food additive chloropentafluoroethane may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a purity of not less than 99.97 percent, and contains not more than 200 parts per million saturated fluoro compounds and 10 parts per million unsaturated fluoro compounds as impurities.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, propane, and octafluorocyclobutane complying with § 173.360, as an aerating agent for foamed or sprayed food products, with any propellant effect being incidental and no more than is minimally necessary to achieve the aerating function, except that use is not permitted for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, chloropentafluoroethane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 11317, Mar. 17, 1978; 43 FR 14644, Apr. 7, 1978]

§ 173.350 Combustion product gas.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment shall be provided with an absorption-type filter capable of removing possible toxic impurities, through which all gas used in the treatment of food shall pass; and with suitable controls to insure that any combustion products failing to meet the specifications provided in this section will be prevented from reaching the food being treated.

(b) The food additive meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the standard reference absorbance when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

(d) To assure safe use of the additive in addition to the other information required by the act, the label or labeling of the combustion device shall bear adequate directions for use to provide a combustion product gas that complies with the limitations prescribed in paragraph (b) of this section, including instructions to assure proper filtration.

(e) The food additive is tested for compliance with paragraph (b)(2) by the following empirical method:

Spectrophotometric measurements. All measurements are made in an ultraviolet spectrophotometer in optical cells of 5 centimeters in length, and in the range of 255 millimicrons to 310 millimicrons, under the same instrumental conditions. The standard reference absorbance is the absorbance at 275 millimicrons of a standard reference solution of naphthalene (National Bureau of Standards Material No. 577 or equivalent in purity) containing a concentration of 1.4 milligrams per liter in purified isooctane, measured against isooctane of the same spectral purity in 5-centimeter cells. (This absorbance will be approximately 0.30.)

Solvent. The solvent used is pure grade isooctane having an ultraviolet absorbance not to exceed 0.05 measured against distilled water as a reference. Upon passage of purified inert gas through some isooctane under the identical conditions of the test, a lowering of the absorbance value has been observed. The absorbance of isooctane to be used in this procedure shall not be more than 0.02 lower in the range 255 millimicrons to 310 millimicrons, inclusive, than that of the untreated solvent as measured in a 5-centimeter cell. If necessary to obtain the prescribed purities, the isooctane may be passed through activated silica gel.

Apparatus. To assure reproducible results, the additive is passed into the isooctane solution through a gas-absorption train consisting of the following components and necessary connections:

1. A gas flow meter with a range up to 30 liters per hour provided with a constant differential relay or other device to maintain a constant flow rate independent of the input pressure.

2. An absorption apparatus consisting of an inlet gas dispersion tube inserted to the bottom of a covered cylindrical vessel with a

suitable outlet on the vessel for effluent gas. The dimensions and arrangement of tube and vessel are such that the inlet tube introduces the gas at a point not above 5¼ inches below the surface of the solvent through a sintered glass outlet. The dimensions of the vessel are such, and both inlet and vessel are so designed, that the gas can be bubbled through 60 milliliters of isooctane solvent at a rate up to 30 liters per hour without mechanical loss of solvent. The level corresponding to 60 milliliters should be marked on the vessel.

3. A cooling bath containing crushed ice and water to permit immersion of the absorption vessel at least to the solvent level mark.

Caution. The various parts of the absorption train must be connected by gas-tight tubing and joints composed of materials which will neither remove components from nor add components to the gas stream. The gas source is connected in series to the flow-rate device, the flow meter, and the absorption apparatus in that order. Ventilation should be provided for the effluent gases which mav contain carbon monoxide.

Sampling procedure. Immerse the gas-absorption apparatus containing 60 milliliters of isooctane in the coolant bath so that the solvent is completely immersed. Cool for at least 15 minutes and then pass 120 liters of the test gas through the absorption train at a rate of 30 liters per hour or less. Maintain the coolant bath at 0° C throughout. Remove the absorption vessel from the bath, disconnect, and warm to room temperature. Add isooctane to bring the contents of the absorption vessel to 60 milliliters, and mix. Determine the absorbance of the solution in the 5-centimeter cell in the range 255 millimicrons to 310 millimicrons, inclusive, compared to isooctane. The absorbance of the solution of combustion product gas shall not exceed that of the isooctane solvent at any wavelength in the specified range by more than one-third of the standard reference absorbance.

§ 173.355 Dichlorodifluoromethane.

The food additive dichlorodifluoromethane may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a purity of not less than 99.97 percent.

(b) It is used or intended for use, in accordance with good manufacturing practice, as a direct-contact freezing agent for foods.

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, dichlorodifluoromethane, with or without the parenthetical name "Food Freezant 12".

(ii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

Fixing agents may be safely used in the immobilization of enzyme preparations in accordance with the following conditions:

(a) The materials consist of one or more of the following:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
Diethylaminoethyl-cellulose.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Glutaraldehyde	Do.

(b) The fixed enzyme preparation is washed to remove residues of the fixing materials.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[48 FR 5716, Feb. 8, 1983]

§ 173.360 Octafluorocyclobutane.

The food additive octafluorocyclobutane may be safely used as a propellant and aerating agent in foamed or sprayed food products in accordance with the following conditions:

(a) The food additive meets the following specifications:

99.99 percent octafluorocyclobutane.

Less than 0.1 part per million fluoroolefins, calculated as perfluoroisobutylene.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, and propane, as a propellant and aerating agent for foamed or sprayed food products, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive:

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, octafluorocyclobutane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.385 Sodium methyl sulfate.

Sodium methyl sulfate may be present in pectin in accordance with the following conditions.

(a) It is present as the result of methylation of pectin by sulfuric acid and methyl alcohol and subsequent treatment with sodium bicarbonate.

(b) It does not exceed 0.1 percent by weight of the pectin.

§ 173.395 Trifluoromethane sulfonic acid.

Trifluoromethane sulfonic acid has the empirical formula CF_3SO_3H (CAS Reg. No. 1493-13-6). The catalyst (Trifluoromethane sulfonic acid) may safely be used in the production of cocoa butter substitute from palm oil (1-palmitoyl-2-oleoyl-3-stearin) (see § 184.1259 of this chapter) in accordance with the following conditions:

(a) The catalyst meets the following specifications:

Appearance, Clear liquid.
Color, Colorless to amber.
Neutralization equivalent, 147-151.
Water, 1 percent maximum.
Fluoride ion, 0.03 percent maximum.
Heavy metals (as Pb), 30 parts per million maximum.
Arsenic (as As), 3 parts per million maximum.

(b) It is used at levels not to exceed 0.2 percent of the reaction mixture to catalyze the directed esterification.

(c) The esterification reaction is quenched with steam and water and the catalyst is removed with the aqueous phase. Final traces of catalyst are removed by washing batches of the product three times with an aqueous solution of 0.5 percent sodium bicarbonate.

(d) No residual catalyst may remain in the product at a detection limit of 0.2 part per million fluoride as determined by the method described in "Official Methods of Analysis of the Association of Official Analytical Chemists," sections 25.049-25.055, 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[43 FR 54237, Nov. 11, 1978, as amended at 49 FR 10106, Mar. 19, 1984]

PART 174—INDIRECT FOOD ADDITIVES: GENERAL

§ 174.5 General provisions applicable to indirect food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purpose of this part and Parts 175, 176, and 177 of this chapter, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of any food additive substance that may be added to food as a result of use in articles that contact food shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself, except as such may be permitted by regulations in Parts 170 through 189 of this chapter.

(2) Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use.

(b) The existence in the Subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed to relieve such use of the substance or article from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act. For example, if a regulated food-packaging material were found on appropriate test to impart odor or taste to a specific food product such as to render it unfit within the meaning of section 402(a)(3) of the Act, the regulation would not be construed to relieve such use from compliance with section 402(a)(3).

(c) The existence in this Subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.

(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

(1) Substances generally recognized as safe in or on food.

(2) Substances generally recognized as safe for their intended use in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances permitted for use by regulations in this part and Parts 175, 176, 177, 178 and § 179.45 of this chapter.

(Sec. 409, 72 Stat. 1785, 1786, as amended (21 U.S.C. 348, 371))

[42 FR 14534, Mar. 15, 1977]

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Adhesives

Sec.

175.105 Adhesives.
175.125 Pressure-sensitive adhesives.

Sec.

Subpart C—Substances for Use as Components of Coatings

175.210 Acrylate ester copolymer coatings.
175.230 Hot-melt strippable food coatings.
175.250 Paraffin (synthetic)
175.260 Partial phosphoric acid esters of polyester resins.
175.270 Poly(vinyl fluoride) resins.
175.300 Resinous and polymeric coatings.
175.320 Resinous and polymeric coatings for polyolefin films.
175.350 Vinyl acetate/crotonic acid copolymer.
175.360 Vinylidene chloride copolymer coatings for nylon film.
175.365 Vinylidene chloride copolymer coatings for polycarbonate film.
175.380 Xylene-formaldehyde resins condensed with 4,4′-isopropylidenediphenol-epichlorohydrin epoxy resins.
175.390 Zinc-silicon dioxide matrix coatings.

AUTHORITY: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C 321(s), 348); 21 CFR 5.10 and 5.61.

SOURCE: 42 FR 14534, Mar. 15, 1977, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Adhesives

§ 175.105 Adhesives.

(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations.

(2) The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:

(i) *In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.

(ii) *In fatty and aqueous foods.* (*a*) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

(*b*) Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

(b) To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement "food-packaging adhesive".

(c) Subject to any limitation prescribed in this section and in any other regulation promulgated under section 409 of the Act which prescribes safe conditions of use for substances that may be employed as constituents of adhesives, the optional substances used in the formulation of adhesives may include the following:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances permitted for use in adhesives by prior sanction or approval and employed under the specific conditions of use prescribed by such sanction or approval.

(3) Flavoring substances permitted for use in food by regulations in this part, provided that such flavoring substances are volatilized from the adhesives during the packaging fabrication process.

(4) Color additives approved for use in food.

(5) Substances permitted for use in adhesives by other regulations in this subchapter and substances named in this subparagraph: *Provided, however,* That any substance named in this paragraph and covered by a specific regulation in this subchapter, must meet any specifications in such regulation.

Substances	Limitations
Abietic acid	
Acetone	
Acetone-formaldehyde condensate (CAS Reg. No. 25619-09-4)	
Acetone-urea-formaldehyde resin	
N-Acetyl ethanolamine	
Acetyl tributyl citrate	
Acetyl triethyl citrate	
Albumin, blood	
(2-Alkenyl) succinic anhydrides in which the alkenyl groups are derived from olefins which contain not less than 78 percent C_{30} and higher groups (CAS Reg. No. 70983-55-0).	
4-[2-[2-2-(Alkoxy (C_{12}–C_{14}))ethoxy) ethoxy]ethyl] disodium sulfosuccinate.	
1-Alkyl (C_6–C_{18}) amino-3-amino-propane monoacetate	
Alkylated (C_4 and/or C_8) phenols	
Alkyl (C_7–C_{12}) benzene	
Alkyl (C_{10}–C_{20}) dimethylbenzyl ammonium chloride	
n-Alkyl(C_{12}, C_{14}, C_{16}, or C_{18}) dimethyl (ethylbenzyl) ammonium cyclohexylsulfamate.	For use as preservative only.
Alkyl ketene dimers as described in § 176.120 of this chapter	
Alkyl (C_7–C_{12}) naphthalene	
alpha Olefin sulfonate [alkyl group is in the range of C_{10}–C_{18} with not less than 50 percent C_{14}–C_{16}], ammonium, calcium, magnesium, potassium, and sodium salts.	
2-[(2-aminoethyl)amino]ethanol (CAS Reg. No. 111-41-1)	
3-Aminopropanediol	For use only in the preparation of polyurethane resins.
Aluminum	
Aluminum acetate	
Aluminum di(2-ethylhexoate)	
Aluminum potassium silicate	
N-*β*-Aminoethyl-*gamma*-aminopropyl trimethoxysilane	
3-(Aminomethyl)-3,5,5-trimethylcyclohexylamine	
Aminomethylpropanol	
Ammonium benzoate	For use as preservative only.
Ammonium bifluoride	For use only as bonding agent for aluminum foil, stabilizer or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Ammonium borate	
Ammonium citrate	
Ammonium persulfate	
Ammonium polyacrylate	
Ammonium potassium hydrogen phosphate	

Substances	Limitations
Ammonium silico-fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Ammonium sulfamate	
Ammonium thiocyanate	
Ammonium thiosulfate	
Amyl acetate	
Anhydroenneaheptitol	
Animal glue as described in § 178.3120 of this chapter	
2-Anthraquinone sulfonic acid, sodium salt	For use only as polymerization-control agent.
Antimony oxide	
Asbestos	
Asphalt, paraffinic and naphthenic	
Azelaic acid	
Azo-*bis*-isobutyronitrile	
Balata rubber	
Barium acetate	
Barium peroxide	
Barium sulfate	
Bentonite	
Benzene (benzol)	
1,4-Benzenedicarboxylic acid, bis[2-(1,1-dimethylethyl)-6-[[3-(1,1-dimethylethyl)-2-hydroxy-5-methylphenyl]methyl]-4-methylphenyl]ester (CAS Reg. No. 57569-40-1)	For use as a stabilizer.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5)	For use as preservative only.
Benzothiazyldisulfide	
p-Benzoxyphenol	For use as preservative only.
Benzoyl peroxide	
Benzyl alcohol	
Benzyl benzoate	
Benzyl bromoacetate	For use as preservative only.
p-Benzyloxyphenol	Do.
BHA (butylated hydroxyanisole)	
BHT (butylated hydroxytoluene)	
Bicyclo[2.2.1]hept-2-ene-6-methyl acrylate	
2-Biphenyl diphenyl phosphate	
1,3-Bis(2-benzothiazolylmercaptomethyl) urea	
4,4′-Bis(*α*,*α*-dimethylbenzyl)diphenylamine	
2,6-Bis(1,1-dimethylethyl)-4-(1-methylpropyl)phenol (CAS Reg. No. 17540-75-9).	For use as an antioxidant and/or stabilizer only.
2,6-Bis (1-methylheptadecyl)-*p*-cresol	
4-[[4, 6-Bis(octylthio)6-Bis(octylthio)6-Bis(octylthio)-*s*-triazin-2-yl]amino]-2,6-di-*tert*-butylphenol (CAS Reg. No. 991-84-4).	
Bis(tri-*n*-butyltin) oxide	For use as preservative only.
Bis(trichloromethyl)sulfone C.A. Registry No. 3064-70-8	Do.
Borax	
Boric acid	
2-Bromo-2-nitro-1, 3-propanediol (CAS Reg. No. 52-51-7)	For use only as an antibacterial preservative.
1,3-Butanediol	
1,4-Butanediol	
1,4-Butanediol modified with adipic acid	
Butoxy polyethylene polypropylene glycol (molecular weight 900-4,200).	
Butyl acetate	
Butyl acetyl ricinoleate	
Butyl alcohol	
Butylated reaction product of *p*-cresol and dicyclopentadiene	As identified in § 178.2010(b) of this chapter.
Butylated, styrenated cresols identified in § 178.2010(b) of this chapter.	
Butyl benzoate	
Butyl benzyl phthalate	
Butyldecyl phthalate	
1,3-Butylene glycoldiglycolic acid copolymer	
tert-Butyl hydroperoxide	
4,4′-Butylidenebis(6-*tert*-butyl-*m*-cresol)	
Butyl lactate	
Butyloctyl phthalate	
p-*tert*-Butylphenyl salicylate	
Butyl phthalate butyl glycolate	
p-*tert*-Butylpyrocatechol	For use only as polymerization-control agent.
Butyl ricinoleate	
Butyl rubber polymer	

Substances	Limitations
Butyl stearate	
Butyl titanate, polymerized	
Butyraldehyde	
Calcium ethyl acetoacetate	
Calcium nitrate	
Calcium metasilicate	
Camphor	
Camphor fatty acid esters	
Candelilla wax	
epsilon-Caprolactam-(ethylene-ethyl acrylate) graft polymer	
Carbon black, channel process	
Carbon disulfide-1,1′-methylenedipiperidine reaction product	
Carbon tetrachloride	
Carboxymethylcellulose	
Castor oil, polyoxyethylated (4–84 moles ethylene oxide)	
Cellulose acetate butyrate	
Cellulose acetate propionate	
Ceresin wax (ozocerite)	
Cetyl alcohol	
Chloracetamide	
Chloral hydrate	
Chlorinated liquid *n*-paraffins with chain lengths of C_{10}–C_{17}, containing 40–70 percent chlorine by weight.	
Chlorinated pyridine mixture with active ingredients consisting of 2,3,5,6-tetrachloro-4-(methylsulfonyl) pyridine, 2,3,5,6-tetrachloro-4-(methylsulfinyl) pyridine and pentachloropyridine.	For use as preservative only.
Chlorinated rubber polymer (natural rubber polymer containing approximately 67 percent chlorine).	
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	For use as preservative only.
Chlorobenzene	
4-Chloro-3,5-dimethylphenol (*p*-chloro-*m*-xylenol)	For use as preservative only.
4-Chloro-3-methylphenol	Do.
5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture at a ratio of 3 parts to 1 part, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2). The mixture may contain magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent in polymer latex emulsions.
Chloroform	
Chloroprene	
Chromium caseinate	
Chromium nitrate	
Chromium potassium sulfate	
Cobaltous acetate	
Coconut fatty acid amine salt of tetrachlorophenol	For use as preservative only.
Copal	
Copper 8-quinolinolate	For use as preservative only.
Coumarone-indene resin	
Cresyl diphenyl phosphate	
Cumene hydroperoxide	
Cyanoguanidine	
Cyclized rubber as identified in § 176.170(b)(2) of this chapter	
Cyclohexane	
Cyclohexanol	
Cyclohexanone resin	
Cyclohexanone-formaldehyde condensate	
N-Cyclohexyl *p*-toluene sulfonamide	
Dammar	
Defoaming agents as described in § 176.210 of this chapter	
Dehydroacetic acid	
Diacetone alcohol	
Diacetyl peroxide	
N,N′-Dialkoyl-4,4′-diaminodiphenylmethane mixtures where the alkoyl groups are derived from marine fatty acids (C_{12}–C_{24}).	
2,5-Di-*tert*-amylhydroquinone	
Diamines derived from dimerized vegetable oil acids	
Diaryl-*p*-phenylenediamine, where the aryl group may be phenyl, tolyl, or xylyl.	
1,2-Dibromo-2,4-dicyanobutane (CAS Registry No. 3569-65-7)	For use as a preservative only.
Di(butoxyethyl) phthalate	
2,5-Di-*tert*-butylhydroquinone	
Dibutyl maleate	

Substances	Limitations
2,6-Di-*tert*-butyl-4-methylphenol	For use as preservative only.
Di(C_7, C_9-alkyl)adipate	
Dibutyl phthalate	
Dibutyl sebacate	
Dibutyltin dilaurate for use only as a catalyst for polyurethane resins	
1,2-Dichloroethylene (mixed isomers)	
Dicumyl peroxide	
Dicyclohexyl phthalate	
Diethanolamine	
Diethanolamine condensed with animal or vegetable fatty acids	
Diethylamine	
Diethylene glycol	
Diethylene glycol adipic acid copolymer	
Diethylene glycol dibenzoate	
Diethylene glycol hydrogenated tallowate monoester	
Diethylene glycol laurate	
Diethylene glycol monobutyl ether	
Diethylene glycol monobutyl ether acetate	
Diethylene glycol monoethyl ether	
Diethylene glycol monoethyl ether acetate	
Diethylene glycol monomethyl ether	
Diethylene glycol monooleate	
Diethylene glycol monophenyl ether	
Diethylene glycol copolymer of adipic acid and phthalic anhydride	
Di(2-ethylhexyl) adipate	
Di(2-ethylhexyl)hexahydrophthalate	
Di(2-ethylhexyl)phthalate	
Diethyl oxalate	
Diethyl phthalate	
Dihexyl phthalate	
Dihydroabietylphthalate	
Di(2-hydroxy-5-*tert*-butylphenyl) sulfide	
2,2′-Dihydroxy-5,5′-dichlorodiphenylmethane (dichlorophene)	
4,5-Dihydroxy-2-imidazolidinone	
4-(Diiodomethylsulfonyl) toluene CA Registry No.: 20018-09-01	For use as an antifungal preservative only.
Diisobutyl adipate	
Diisobutyl ketone	
Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride	
Diisobutyl phthalate	
Diisodecyl adipate	
Diisodecyl phthalate	
Diisooctyl phthalate	
Diisopropylbenzene hydroperoxide	
N,N-Dimethylcyclohexylamine dibutyldithiocarbamate	
Dimethyl formamide	
Dimethyl hexynol	
2,2-Dimethyl-1,3-propanediol dibenzoate	
Dimethyl octynediol	
N-(1,1-dimethyl-3-oxobutyl) acrylamide	
Dimethyl phthalate	
3 5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione	For use as preservative only.
Di-*β*-naphthyl-*p*-phenylenediamine	
4,6-Dinonyl-*o*-cresol	
Dinonylphenol	
Di-*n*-octyldecyl adipate	
Dioctyldiphenylamine	
Dioctylphthalate	
Dioctylsebacate	
Dioxane	
Dipentaerythritol pentastearate	
Dipentamethylenethiuram-tetrasulfide	
Dipentene	
Dipentene resins	
Dipentene-*beta*-pinene-styrene resins	
Dipentene-styrene resin (CAS Registry No. 64536-06-7)	
Diphenyl-2-ethylhexyl phosphate	
Diphenyl, hydrogen ated	
N,N′-Diphenyl-*p*-phenylenediamine	
Diphenyl phthalate	
1,3-Diphenyl-2-thiourea	
Dipropylene glycol	
Dipropylene glycol dibenzoate	
Dipropylene glycol monomethyl ether	

Substances	Limitations
Dipropylene glycol copolymer of adipic acid and phthalic anhydride	
Disodium cyanodithioimidocarbonate	
N,N'-Distearoylethylenediamine	
Distearyl thiodipropionate	
3,5-Di-*tert*-butyl-4-hydroxyhydrocinnamic acid triester with 1,3,5-tris(2-hydroxyethyl)-*s*-triazine-2,4,6(1*H*, 3*H*, 5*H*)-trione.	For use as antioxidant only.
4,4'-Dithiodimorpholine	
n-Dodecylmercaptan	
tert-Dodecylmercaptan	
Dodecylphenoxybenzene-disulfonic acid and/or its calcium, magnesium, and sodium salts.	
Elemi gum	
Epichlorohydrin-4,4'-isopropylidenediphenol resin	
Epichlorohydrin-4,4'-*sec*-butylidenediphenol resin	
Epichlorohydrin-4,4'-isopropylidene-di-o-cresol resin	
Epichlorohydrin-phenolformaldehyde resin	
Erucamide (erucylamide)	
Ethanolamine	
Ethoxypropanol butyl ether	
Ethyl alcohol (ethanol)	
5-Ethyl-1,3-diglycidyl-5-methylhydantoin (CAS Reg. No. 15336-82-0)	
Ethylenediamine	
Ethylenediaminetetra-acetic acid, calcium, ferric, potassium, or sodium salts, single or mixed.	
Ethylene dichloride	
Ethylene glycol	
Ethylene glycol monobutyl ether	
Ethylene glycol monobutyl ether acetate	
Ethylene glycol monoethyl ether	
Ethylene glycol monoethyl ether acetate	
Ethylene glycol monoethyl ether ricinoleate	
Ethylene glycol monomethyl ether	
Ethylene glycol monophenyl ether	
Ethylene-carbon monoxide copolymer (CAS Reg. No. 25052-62-4) containing not more than 30 weight percent of the units derived from carbon monoxide.	
Ethylene-maleic anhydride copolymer, ammonium or potassium salt	
Ethylene-methacrylic acid copolymer partial salts: Ammonium, calcium, magnesium, sodium, and/or zinc.	
Ethylene-methacrylic acid-vinyl acetate copolymer partial salts: Ammonium, calcium, magnesium, sodium, and/or zinc.	
Ethylene-propylene-dicyclopentadiene copolymer rubber	
Ethylene, propylene, 1,4-hexadiene and 2,5-norbornadiene tetrapolymer.	
Ethylene-vinyl acetate carbon monoxide terpolymer (CAS Registry No. 26337-35-9) containing not more than 15 weight percent of units derived from carbon monoxide.	
2,2'-Ethylidenebis (4,6-di-*tert*-butylphenol) (CAS Reg. No. 35958-30-6).	
Ethyl-*p*-hydroxybenzoate	For use as preservative only.
Ethyl hydroxyethylcellulose	
Ethyl lactate	
Ethyl phthalyl ethyl glycolate	
Ethyl-*p*-toluene sulfonamide	
Fats and oils derived from animal or vegetable sources, and the hydrogenated, sulfated, or sulfonated forms of such fats and oils.	
Fatty acids derived from animal or vegetable fats and oils; and salts of such acids, single or mixed, as follows:	
Aluminum	
Ammonium	
Calcium	
Magnesium	
Potassium	
Sodium	
Zinc	
Ferric chloride	
Fluosilicic acid (hydrofluosilicic acid)	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Formaldehyde	
Formaldehyde *o*- and *p*-toluene sulfonamide	
Formamide	

Substances	Limitations
Fumaratochromium (III) nitrate	
Furfural	
Furfuryl alcohol	
Fumaric acid	
gamma-Aminopropyltrimethoxysilane (CAS Reg. No. 13822-56-5)	
Glutaraldehyde	
Glycerides, di- and monoesters	
Glyceryl borate (glycol boriborate resin)	
Glyceryl ester of damar, copal, elemi, and sandarac	
Glyceryl monobutyl ricinoleate	
Glyceryl monohydroxy stearate	
Glyceryl monohydroxy tallowate	
Glyceryl polyoxypropylene triol (average molecular weight 1,000)	
Glyceryl tribenzoate	
Glycol diacetate	
Glyoxal	
Heptane	
Hexamethylenetetramine	
Hexane	
Hexanetriols	
Hexylene glycol	
Hydroabietyl alcohol	
Hydrocarbon resins (produced by polymerization of mixtures of mono- and di-unsaturated hydrocarbons of the aliphatic, alicyclic, and monobenzenoid type derived both from cracked petroleum and terpene stocks) (CAS Reg. No. 68239-99-6).	
Hydrocarbon resins (produced by the polymerization of styrene and *alpha*-methyl styrene), hydrogenated (CAS Reg. No. 68441-37-2).	
Hydrofluoric acid	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Hydrogen peroxide	
α-Hydro-*omega*-hydroxypoly-(oxytetramethylene)	For use only in the preperation of polyurethane resins.
Hydroquinone	
Hydroquinone monobenzyl ether	
Hydroquinone monoethyl ether	
2(2'-Hydroxy-3',5' di-*tert*-amylphenyl) benzotriazole	
Hydroxyacetic acid	
7-Hydroxycoumarin	
Hydroxyethylcellulose	
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2 alkyl (C_6-C_{17}) imidazolinium chloride.	
Hydroxyethyldiethylenetriamine	
β-Hydroxyethyl pyridinium 2-mercaptobenzothiazol	
Hydroxyethyl starch	
Hydroxyethylurea	
Hydroxylamine sulfate	
5-Hydroxymethoxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-hydroxypoly-[methyleneoxy]methyl-1-aza-3,7-dioxabicyclo[3.3.0] octane mixture.	For use only as an antibacterial preservative.
Hydroxypropyl methylcellulose	
2-(Hydroxymethyl)-2-methyl-1,3-propanediol tribenzoate	
2-Imidazolidinone	
Iodoform	For use only as polymerization-control agent.
Isoascorbic acid	
isobuytl alcohol (isobutanol)	
Isobutylene-isoprene copolymer	
Isophorone	
Isopropanolamine (mono-, di-, tri-)	
Isopropyl acetate	
Isopropyl alcohol (isopropanol)	
Isopropyl-*m*- and *p*-cresol (thymol derived)	
4,4'-Isopropylidenediphenol	
4,4'-Isopropylidenediphenol, polybutylated mixture	For use as preservative only.
isopropyl peroxydicarbonate	
p-Isopropoxy diphenylamine	
4,4'-Isopropylidene-bis(*p*-phenyleneoxy)-di-2-propanol	
Itaconic acid	
Japan wax	
Kerosene	
Lauroyl peroxide	

Substances	Limitations
Lauroyl sulfate salts:	
Ammonium	
Magnesium	
Potassium	
Sodium	
Lauryl alcohol	
Lauryl pyridinium 5-chloro-2-mercaptobenzothiazole	
Lignin calcium sulfonate	
Lignin sodium sulfonate	
Linoleamide (linoleic acid amide)	
Magnesium fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesives.
Magnesium glycerophosphate	
Maleic acid	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt	
Manganese acetate	
Marine oil fatty acid soaps, hydrogenated	
Melamine	
Melamine-formaldehyde copolymer	
2-Mercaptobenzothiazole	
2-Mercaptobenzothiazole and dimethyl dithiocarbamic acid mixture, sodium salt.	For use as preservative only.
2-Mercaptobenzothiazole, sodium or zinc salt	For use as preservative only.
Methacrylate-chromic chloride complex, ethyl or methyl ester	
p-Menthane hydroperoxide	
Methyl acetate	
Methyl acetyl ricinoleate	
Methyl alcohol (methanol)	
Methylcellulose	
Methylene chloride	
4,4′-Methylenebis(2,6-di-*tert*-butylphenol)	
2,2-Methylenebis (4-ethyl-6-*tert*-butylphenol)	
2,2-Methylenebis (4-methyl-6-nonylphenol)	
2,2-Methylenebis (4-methyl-6-*tert*-butylphenol)	
Methyl ethyl ketone	
Methyl ethyl ketone-formaldehyde condensate	
2-Methylhexane	
1-Methyl-2-hydroxy-4-isopropyl benzene	
Methyl isobutyl ketone	
Methyl oleate	
Methyl oleate-palmitate mixture	
Methyl phthalyl ethyl glycolate	
Methyl ricinoleate	
Methyl salicylate	
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 *α* methylstyrene to 3 vinyltoluene).	
Methyl tallowate	
Mineral oil	
Monochloracetic acid	
Monooctyldiphenylamine	
Montan wax	
Morpholine	
Myristic acid-chromic chloride complex	
Myristyl alcohol	
Naphtha	
Naphthalene, monosulfonated	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt	
α-Naphthylamine	
α,α′,α″,α‴-Neopentane tetrayltetrakis [*omega*-hydroxypoly (oxypropylene) (1–2 moles)], average molecular weight 400.	
Nitric acid	
μ-Nitrobiphenyl	
Nitrocellulose	
2-Nitropropane	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 6–9 moles or 50 moles.	

Substances	Limitations
α(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of *p*-nonylphenol (nonyl group is a propylene trimer isomer) with an average of 1–40 moles of ethylene oxide.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) sulfate, ammonium salt: the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles.	
endo-cis-5-Norbornene-2,3-dicarboxylic anhydride	
α-*cis*-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles.	
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate	
Octyl alcohol	
Octyldecyl phthalate	
Octylphenol	
Octylphenoxyethanols	
Octylphenoxypolyethoxy-polypropoxyethanol (13 moles of ethylene oxide and propylene oxide).	
Odorless light petroleum hydrocarbons	
Oleamide (oleic acid amide)	
Oleic acid, sulfated	
2,2′-Oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1).	
Oxazoline	
n-Oxydiethylene-benzothiazole	
Palmitamide (palmitic acid amide)	
Paraffin (C_{12}–C_{20}) sulfonate	
Paraformaldehyde	
Pentachlorophenol	
Pentaerythritol ester of maleic anhydride	
Pentaerythritol monostearate	For use as preservative only.
Pentaerythritol tetrabenzoate [CAS Registry No. 4196-86-5]	
Pentaerythritol tetrastearate	
2,4-Pentanedione	
Perchloroethylene	
Petrolatum	
Petroleum hydrocarbon resin (cyclopentadiene type), hydrogenated	
Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).	
Petroleum hydrocarbon resins (produced by the homo-and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks).	
Phenol	For use as preservative only.
Phenol-coumarone-indene resin	
Phenolic resins as described in § 175.300(b)(3)(vi)	
Phenothiazine	For use only as polymerization-control agent.
Phenyl-β-naphthylamine (free of β-naphthylamine)	
o-Phenylphenol	For use as preservative only.
o-Phthalic acid	
Pimaric acid	
Pine oil	
Piperazine	
Piperidinium pentamethylenedithiocarbamate	
Poly(acrylamide-[2-acrylamide-2-methylpropylsulfonate]-dimethyldiallyl ammonium chloride) sodium salt (CAS Reg. No. 72275-68-4).	
Polyamides derived from reaction of one or more of the following acids with one or more of the following amines:	
Acids:	
Azelaic acid	
Dimerized vegetable oil acids	
Amines:	
Bis(hexamethylene) triamine and higher homologues	
Diethylenetriamine	
Diphenylamine	
Ethylenediamine	
Hexamethylenediamine	
Tetraethylenepentamine	
Triethylenetetramine	
Polybutene, hydrogenated	
Polybutylene glycol (molecular weight 1,000)	

Substances	Limitations
Poly [2(diethylamino) ethyl methacrylate] phosphate	
Polyester of adipic acid, phthalic acid, and propylene glycol, terminated with butyl alcohol.	
Polyester of diglycolic acid and propylene glycol containing ethylene glycol monobutyl ether as a chain stopper.	
Polyester resins (including alkyd type), as the basic polymer, formed as esters when one or more of the following acids are made to react with one or more of the following alcohols:	
Acids:	
Azelaic acid	
Dimethyl-5-sulfoisophthalic acid (CAS Reg. No. 50975-82-1) and/or its sodium salt (CAS Reg. No. 3965-55-7).	
Polybasic and monobasic acids identified in § 175.300(b)(3)(vii)(*a*) and (*b*).	
Tetrahydrophthalic acid	
Alcohols:	
1,4-Cyclohexanedimethanol	
2,2-Dimethyl-1,3-propanediol	
1,6-Hexanediol (CAS Reg. No. 629-11-8)	
Polyhydric and monohydric alcohols identified in § 175.300(b)(3)(vii)(*c*) and (*d*).	
Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.	For use only in the preparation of polyurethan resins.
Polyethylene glycol (molecular weight 200-6,000)	
Polyethylene, oxidized	
Polyethylene resins, carboxyl modified, identified in § 177.1600 of this chapter.	
Polyethylenimine	
Polyethylenimine-epichlorohydrin resins	
Polyisoprene	
Polymeric esters of polyhydric alcohols and polycarboxylic acids prepared from glycerin and phthalic anhydride and modified with benzoic acid, castor oil, coconut oil, linseed oil, rosin, soybean oil, styrene, and vinyl toluene.	
Polymers: Homopolymers and copolymers of the following monomers:	
Acrylamide	
Acrylic acid	
Acrylonitrile	
Butadiene	
Butene	
N-tert-Butylacrylamide	
Butyl acrylate	
1,3-Butylene glycol dimethacrylate	
Butyl methacrylate	
Crotonic acid	
Decyl acrylate	
Diallyl fumarate	
Diallyl maleate	
Diallyl phthalate	
Dibutyl fumarate	
Dibutyl itaconate	
Dibutyl maleate	
Di(2-ethylhexyl) maleate	
Dimethyl-α-methylstyrene	
Dioctyl fumarate	
Dioctyl maleate	
Divinylbenzene	
Ethyl acrylate	
Ethylene	
Ethylene cyanohydrin	
2-Ethylhexyl acrylate	
Ethyl methacrylate	
Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl hexyl, heptyl and octyl esters.	
Glycidyl methacrylate	
2-Hydroxyethyl acrylate	
2-Hydroxyethyl methacrylate	
2-Hydroxypropyl methacrylate	
Isobutyl acrylate	
Isobutylene	
Itaconic acid	

Substances	Limitations
Maleic acid, diester with 2-hydroxyethanesulfonic acid, sodium salt.	
Maleic anhydride	
Methacrylic acid	
Methyl acrylate	
N,N'-Methylenebisacrylamide	
Methyl methacrylate	
N-Methylolacrylamide	
Methyl styrene	
-Methyl styrene	
Monoethyl maleate	
Monomethyl maleate	
Mono (2-ethylhexyl) maleate	
5-Norbornene-2 3-dicarboxylic acid, mono-*n*-butyl ester	
Propyl acrylate	
Propylene	
Styrene	
Triallyl cyanurate	
Vinyl acetate	
Vinyl alcohol (from alcoholysis or hydrolysis of vinyl acetate units).	
Vinyl butyrate	
Vinyl chloride	
Vinyl crotonate	
Vinyl ethyl ether	
Vinyl hexoate	
Vinylidene chloride	
Vinyl methyl ether	
Vinyl pelargonate	
Vinyl propionate	
Vinyl pyrrolidone	
Vinyl stearate	
Polyoxyalkylated-phenolic resin (phenolic resin obtained from formaldehyde plus butyl- and/or amylphenols, oxyalkylated with ethylene oxide and/or propylene oxide).	
Poly(oxycaproyl) diols and triols (minimum molecular weight 500)	
Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt	
Polyoxyethylene (20 mol)—anhydrous lanolin adduct	
Polyoxyethylene (molecular weight 200) dibenzoate	
Polyoxyethylene (molecular weight 200–600) esters of fatty acids derived from animal or vegetable fats and oils (including tall oil).	
Polyoxyethylene (15 moles) ester of rosin	
Polyoxyethylene (4–5 moles) ether of phenol	
Polyoxyethylene (25 moles)—glycerol adduct	
Polyoxyethylene (40 moles) stearate	
Polyoxyethylene (5–15 moles) tridecyl alcohol	
Polyoxypropylene (3 moles) tridecyl alcohol sulfate	
Polyoxypropylene (20 moles) butyl ether	
Polyoxypropylene (40 moles) butyl ether	
Polyoxypropylene (20 moles) oleate butyl ether	
Polyoxypropylene-polyoxyethylene condensate (minimum molecular weight 1,900).	
Polypropylene glycol (minimum molecular weight 150)	
Polypropylene glycol (3–4 moles) triether with 2-ethyl-2-(hydroxymethyl)-1,3-propane-diol, average molecular weight 730.	
Polypropylene, noncrystalline	
Polysiloxanes:	
Diethyl polysiloxane	
Dihydrogen polysiloxane	
Dimethyl polysiloxane	
Diphenyl polysiloxane	
Ethyl hydrogen polysiloxane	
Ethyl phenyl polysiloxane	
Methyl ethyl polysiloxane	
Methyl hydrogen polysiloxane	
Methyl phenyl polysiloxane	
Phenyl hydrogen polysiloxane	
Polysorbate 60	
Polysorbate 80	
Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate)	
Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate)	
Poly[styrene-co-disodium maleate-co-α-(*p*-nonyl-phenyl)-*omega*-(*p*-vinyl-benzyl)poly(oxyethylene)] terpolymer.	

Substances	Limitations
Polytretrafluoroethylene	
Polyurethane resins produced by: (1) reacting diisocyanates with one or more of the polyols or polyesters named in this paragraph, or (2) reacting the chloroformate derivatives of one or more of the polyols or polyesters named in this paragraph with one or more of the polyamines named in this paragraph, or (3) reacting toluene diisocyanate or 4,4′-methylenebis(cyclohexylisocyanate) [Chemical Abstracts Service Registry No. 5124-30-1] with one or more of the polyols or polyesters named in this paragraph and with either *N*-methyldiethanolamine [Chemical Abstracts Service Registry No. 105-59-9] and dimethyl sulfate [Chemical Abstracts Service Registry No. 77-78-1] or dimethylolpropionic acid [Chemical Abstracts Service Registry No. 4767-03-7] and triethylamine [Chemical Abstracts Service Registry No. 121-44-8].	
Polyvinyl alcohol modified so as to contain not more than 3 weight percent of comonomer units derived from 1-alkenes having 12 to 20 carbon atoms.	
Polyvinyl butyral	
Polyvinyl formal	
Potassium ferricyanide	For use only as polymerization-control agent.
Potassium *N*-methyldithiocarbamate	
Potassium pentachlorophenate	For use as preservative only.
Potassium permanganate	
Potassium persulfate	
Potassium phosphates (mono-, di-, tribasic)	
Potassium tripolyphosphate	
α, α′, α″-1,2,3-Propanetriyltris [*omega*-(2,3-epoxypropoxy) poly (oxypropylene) (24 moles)].	
β-Propiolactone	
Propyl alcohol (propanol)	
Propylene carbonate	
Propylene glycol and *p-p′*-isopropylidenediphenol diether	
Propylene glycol esters of coconut fatty acids	
Propylene glycol monolaurate	
Propylene glycol monomethyl ether	
Propylene glycol monostearate	
α, α′, α″-[Propylidynetris (methylene)] tris [*omega*-hydroxypoly (oxypropylene) (1.5 moles minimum)], minimum molecular weight 400.	
Quaternary ammonium chloride (hexadecyl, octadecyl derivative)	For use as preservative only.
Rosin (wood, gum, and tall oil rosin), rosin dimers, decarboxylated rosin (including rosin oil, disproportionated rosin, and these substances as modified by one or more of the following reactants:.	
Alkyl (C_1–C_8) phenolformaldehyde	
Ammonia	
Ammonium caseinate-*p*-Cyclohexylphenolformaldehyde	
Diethylene glycol	
Dipentaerythritol	
Ethylene glycol	
Formaldehyde	
Fumaric acid	
Glycerin	
Hydrogen	
Isophthalic acid	
4,4′-Isopropylidenediphenol-epichlorohydrin (epoxy)	
4,4′-Isopropylidenediphenol-formaldehyde	
Maleic anhydride	
Methyl alcohol	
Pentaerythritol	
Phthalic anhydride	
Polyethylene glycol	
Phenol-formaldehyde	
Phenyl μ-cresol-formaldehyde	
p-Phenylphenol-formaldehyde	
Sulfuric acid	
Triethylene glycol	
Xylenol-formaldehyde	
Rosin salts (salts of wood, gum, and tall oil rosin, and the dimers thereof, decarboxylated rosin disproportionated rosin, hydrogenated rosin):	
Aluminum	
Ammonium	
Calcium	
Magnesium	

Substances	Limitations
Potassium	
Sodium	
Zinc	
Rosin, gasoline-insoluble fraction	
Rubber hydrochloride polymer	
Rubber latex, natural	
Salicylic acid	For use as preservative only.
Sandarac	
Sebacic acid	
Shellac	
Silicon dioxide as defined in § 172.480(a) of this chapter	
Sodium alkyl (C_9–C_{15}, aliphatic) benezenesulfonate	
Sodium aluminum pyrophosphate	
Sodium aluminum sulfate	
Sodium bisulfate	
Sodium calcium silicate	
Sodium capryl polyphosphate	
Sodium carboxymethylcellulose	
Sodium chlorate	
Sodium chlorite	
Sodium chromate	
Sodium decylsulfate	
Sodium dehydroacetate	For use as preservative only.
Sodium di-(2-ethylhexoate)	
Sodium di-(2-ethylhexyl) pyrophosphate	
Sodium dihexylsulfosuccinate	
Sodium diisobutylphenoxydiethoxyethyl sulfonate	
Sodium diisobutylphenoxymonoethoxyethyl sulfonate	
Sodium diisopropyl- and triisopropylnaphthalenesulfonate	
Sodium dimethyldithiocarbamate	
Sodium dioctylsulfosuccinate	
Sodium *n*-dodecylpolyethoxy (50 moles) sulfate	
Sodium ethylene ether of nonylphenol sulfate	
Sodium 2-ethylhexyl sulfate	
Sodium fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride for all sources not to exceed 1 percent by weight of the finished adhesive.
Sodium formaldehyde sulfoxylate	
Sodium formate	
Sodium heptadecylsulfate	
Sodium hypochlorite	
Sodium isododecylphenoxypolyethoxy (40 moles) sulfate	
Sodium *N*-lauroyl sarcosinate	
Sodium metaborate	
Sodium α-naphthalene sulfonate	
Sodium nitrate	
Sodium nitrite	
Sodium oleoyl isopropanolamide sulfosuccinate	
Sodium pentachlorophenate	For use as preservative only.
Sodium perborate	
Sodium persulfate	
Sodium μ-phenylphenate	For use as preservative only.
Sodium polyacrylate	
Sodium polymethacrylate	
Sodium polystyrene sulfonate	
Sodium salicylate	For use as preservative only.
Sodium salt of 1-hydroxy 2(1H)-pyridine thione	Do.
Sodium tetradecylsulfate	
Sodium thiocyanate	
Sodium bis-tridecylsulfosuccinate	
Sodium xylene sulfonate	
Sorbitan monooleate	
Sorbitan monostearate	
Soybean oil, epoxidized	
Spermaceti wax	
Sperm oil wax	
Stannous 2-ethylhexanoate	For use only as a catalyst for polyurethane resins.
Stannous stearate	
Starch hydrolysates	
Starch or starch modified by one or more of the treatments described in §§ 172.892 and 178.3520 of this chapter.	
Starch, reacted with a urea-formaldehyde resin	

Substances	Limitations
Starch, reacted with formaldehyde	
Stearamide (stearic acid amide)	
Stearic acid	
Stearic acid-chromic chloride complex	
Stearyl-cetyl alcohol, technical grade, approximately 65 percent–80 percent stearyl and 20 percent–35 percent cetyl.	
Strontium salicylate	
Styrenated phenol	
Styrene block polymers with 1,3-butadiene	
Styrene-maleic anhydride copolymer, ammonium or potassium salt	
Styrene-maleic anhydride copolymer (partially methylated) sodium salt	
Styrene-methacrylic acid copolymer, potassium salt	
Sucrose acetate isobutyrate	
Sucrose benzoate	
Sucrose octaacetate	
2–sulfoethyl methacrylate (CAS Registry No. 10595–80–9)	For use at levels not to exceed 2 percent by weight of the dry adhesive.
α-Sulfo-omega-(dodecyloxy)poly (oxyethylene), ammonium salt	
Sulfonated octadecylene (sodium form)	
Sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether disodium salt (alcohol moiety produced by condensation of 1 mole of *n*-dodecyl alcohol and an average of 5–6 moles of ethylene oxide, Chemical Abstracts Service Registry No. 039354–45–5).	
Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole of nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).	
Sulfur	
Synthetic wax polymer as described in § 176.170(a)(5) of this chapter	
Tall oil	
Tall oil fatty acids, linoleic and oleic	
Tall oil fatty acid methyl ester	
Tall oil, methyl ester	
Tall oil pitch	
Tall oil soaps	
Tallow alcohol (hydrogenated)	
Tallow amine, secondary (hexadecyl, octadecyl), of hard tallow	
Tallow, blown (oxidized)	
Tallow, propylene glycol ester	
Terpene resins (α-and β-pinene) homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.	
Terphenyl	
Terphenyl, hydrogenated	
Terpineol	
Tetraethylene pentamine	
Tetraethylthiuram disulfide	
Tetrahydrofuran	
Tetrahydrofurfuryl alcohol	
Tetra-isopropyl titanate	
Tetrakis[methylene (3,5-di-*tert*-butyl-4-hydroxy-hydro-cinnamate)] methane.	
A[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly-(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 1–40 moles of ethylene oxide.	
A-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxy-poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles.	
Tetramethyl decanediol	
Tetramethyl decynediol	
Tetramethyl decynediol plus 1–30 moles of ethylene oxide	
Tetramethylthiuram monosulfide	
Tetrasodium *N*-(1,2-dicarboxyethyl)*N*-octadecylsulfosuccinamate	
4,4′-Thiobis-6-*tert*-butyl-*m*-cresol	
Thiodiethylene-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)	
2,2′-(2,5-Thiophenediyl) bis[5-*tert*-butylbenzoxazole]	
Thiram	
Thymol	For use as preservative only.
Titanium dioxide	
Titanium dioxide-barium sulfate	
Titanium dioxide-calcium sulfate	

Substances	Limitations
Titanium dioxide-magnesium silicate	
Toluene	
Toluene 2,4-diisocyanate	
Toluene 2,6-diisocyanate	
o- and *p*-Toluene ethyl sulfonamide	
o- and *p*-Toluene sulfonamide	
p-Toluene sulfonic acid	
p- (*p'*-Toluene-sulfonylamide)-diphenylamide	
Triazine-formaldehyde resins as described in § 175.300(b)(3)(xiii)	
Tributoxyethyl phosphate	
Tributylcitrate	
Tri-*tert*-butyl-*p*-phenyl phenol	For use as preservative only.
Tributyl phosphate	
Tributyltin chloride complex of ethylene oxide condensate of dehydroabietylamine.	For use as preservative only.
Tri-*n*-butyltin acetate	For use as preservative only.
Tri-*n*-butyltin neodecanoate	Do.
1,1,1-Trichloroethane	
1,1,2-Trichloroethane	
Trichloroethylene	
Tri-*β*-chloroethylphosphate	
Tridecyl alcohol	
Triethanolamine	
3-(Triethoxysilyl) propylamine	
Triethylene glycol	
Triethylene glycol dibenzoate	
Triethylene glycol di(2-ethylhexoate)	
Triethylene glycol polyester of benzoic acid and phthalic acid	
Triethylhexyl phosphate	
Triethylphosphate	
2,4,5-Trihydroxy butyrophenone	
Triisopropanolamine	
Trimethylol propane	
2,2,4-Trimethylpentanediol-1,3-diisobutyrate	
Trimeric aromatic amine resin from diphenylamine and acetone of molecular weight approximately 500.	
Tri(nonylphenyl) phosphite-formaldehyde resins	As identified in § 177.2600(c)(4)(iii) of this chapter. For use only as a stabilizer.
Triphenylphosphate	
Tripropylene glycol monomethyl ether	
1,3,5-Tris (3,5-di-*tert*-butyl-4-hydroxy-benzyl)-triazine-2,4,6 (1H,3H,5H)-trione.	
Tris (*p*-tertiary butyl phenyl) phosphate	
Tris(2-methyl-4-hydroxy-5-*tert*-butyl-phenyl)butane	
Turpentine	
Urea-formaldehyde resins as described in § 175.300(b)(3)(xii)	
Vegetable oil, sulfonated or sulfated, potassium salt	
Vinyl acetate-maleic anhydride copolymer, sodium salt	
Waxes, petroleum	
Wax, petroleum, chlorinated (40% to 70% chlorine)	
Waxes, synthetic paraffin (Fischer-Tropsch process)	
3-(2-Xenolyl)-1,2-epoxypropane	
Xylene	
Xylene (or toluene) alkylated with dicyclopentadiene	
Zein	
Zinc acetate	
Zinc ammonium chloride	
Zinc dibenzyl dithiocarbamate	
Zinc dibutyldithiocarbamate	
Zinc diethyldithiocarbamate	
Zinc di(2-ethylhexoate)	
Zinc formaldehyde sulfoxylate	
Zinc naphthenate and dehydroabietylamine mixture	
Zinc nitrate	
Zinc orthophosphate	
Zinc resinate	
Zinc sulfide	
Zineb (zinc ethylenebis-dithiocarbamate)	
Ziram (zinc dimethyldithiocarbamate)	

[42 FR 14534, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting § 175.105, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 175.125 Pressure-sensitive adhesives.

Pressure-sensitive adhesives may be safely used as the food-contact surface of labels and/or tapes applied to food, in accordance with the following prescribed conditions:

(a) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to poultry, dry food, and processed, frozen, dried, or partially dehydrated fruits or vegetables.

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with a prior sanction or approval.

(3) Color additives listed for use in or on food in Parts 73 and 74 of this chapter.

(4) Substances identified in § 172.615 of this chapter other than substances used in accordance with paragraph (a)(2) of this section.

(5) Polyethylene, oxidized; complying with the identity prescribed in § 177.1620(a) of this chapter.

(6) 4-[[4, 6-Bis(octylthio)-*s*-triazin-2-yl]amino]-2,6-di-*tert*-butylphenol (CAS Reg. No. 991-84-4) as an antioxidant/stabilizer at a level not to exceed 1.5 percent by weight of the finished pressure-sensitive adhesive.

(b) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to raw fruit and raw vegetables.

(1) Substances listed in paragraphs (a)(1), (2), (3), (5), and (6) of this section, and those substances prescribed by paragraph (a)(4) of this section that are not identified in paragraph (b)(2) of this section.

(2) Substances identified in this subparagraph and subject to the limitations provided:

BHA.
BHT.
Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
Chlorinated natural rubber.
Isobutylene-styrene copolymer.
Petrolatum.
Polybutene-1.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.
Polyisobutylene.
cis-1,4-Polyisoprene.
Polystyrene.
Propyl gallate.
Rapeseed oil, vulcanized.
Rosins and rosin derivatives as provided in § 178.3870 of this chapter.
Rubber hydrochloride.
Rubber (natural latex solids or crepe, smoked or unsmoked).
Terpene resins (α- and β-pinene), homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.
Tetrasodium ethylenediaminetetraacetate.
Tri(mixed mono- and dinonylphenyl) phosphite (which may contain not more than 1 percent by weight of triisopropanolamine).

(c) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 48 FR 15617, Apr. 12, 1983]

Subpart C—Substances for Use as Components of Coatings

§ 175.210 Acrylate ester copolymer coating.

Acrylate ester copolymer coating may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food, subject to the provisions of this section:

(a) The acrylate ester copolymer is a fully polymerized copolymer of ethyl acrylate, methyl methacrylate, and methacrylic acid applied in emulsion form to molded virgin fiber and heat-cured to an insoluble resin.

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the emulsion may include substances named in this paragraph, in an amount not to exceed that required to accomplish the desired technical effect and subject to any limitation prescribed: *Provided, however,* That any substance named in this paragraph and covered by a specific regulation in Subchapter B of this chapter must meet any specifications in such regulation.

List of substances	Limitations
Aluminum stearate	
Ammonium lauryl sulfate	
Borax	Not to exceed the amount required as a preservative in emulsion defoamer.
Disodium hydrogen phosphate	Do.
Formaldehyde	
Glyceryl monostearate	
Methyl cellulose	
Mineral oil	
Paraffin wax	
Potassium hydroxide	
Potassium persulfate	
Tallow	
Tetrasodium pyrophosphate	
Titanium dioxide	

(c) The coating in the form in which it contacts food meets the following tests:

(1) An appropriate sample when exposed to distilled water at 212° F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

(2) An appropriate sample when exposed to n-heptane at 120° F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

§ 175.230 Hot-melt strippable food coatings.

Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section.

(a) The coatings are applied to and used as removable coatings for food.

(b) The coatings may be prepared, as mixtures, from the following substances:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetylated monoglycerides	Complying with 172.828 of this chapter.
Cellulose acetate butyrate	
Cellulose acetate propionate	
Mineral oil, white	For use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with § 172.878 of this chapter.

§ 175.250 Paraffin (synthetic).

Synthetic paraffin may be safely used as an impregnant in, coating on, or component of coatings on articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The additive is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular-weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. This mixture can be fractionated into its components by a solvent separation method, using synthetic isoparaffinic petroleum hydrocarbons complying with § 178.3530 of this chapter.

(b) Synthetic paraffin shall conform to the following specifications:

(1) *Congealing point.* There is no specification for the congealing point of synthetic paraffin components, except those components that have a congealing point below 93° C when used in contact with food Types III, IVA, V, VIIA, and IX identified in Table 1 of § 176.170(c) of this chapter and under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter shall be limited to a concentration not exceeding 15 percent by weight of the finished coating. The congealing point shall be determined by ASTM method D938-71 (Reapproved 1981), "Standard Test Method for Congealing Point of Petroleum Waxes, Including Petrolatum," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the

Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Oil content.* The substance has an oil content not exceeding 0.5 percent as determined by ASTM method D721-56T, "Tentative Method of Test for Oil Content of Petroleum Waxes" (Revised 1956), which is incorporated by reference. See paragraph (b)(1) of this section for availability of the incorporation by reference.

(3) *Absorptivity.* The substance has an absorptivity at 290 millimicrons in decahydronaphthalene at 88° C not exceeding 0.01 as determined by ASTM method E131-81a, "Standard Definitions of Terms and Symbols Relating to Molecular-Spectroscopy," which is incorporated by reference. See paragraph (b)(1) of this section for availability of the incorporation by reference.

(c) The provisions of this section are not applicable to synthetic paraffin used in food-packaging adhesives complying with § 175.105.

[42 FR 14534, Mar. 15, 1977, as amended at 47 FR 11839, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 51 FR 47010, Dec. 30, 1986]

§ 175.260 Partial phosphoric acid esters of polyester resins.

Partial phosphoric acid esters of polyester resins identified in this section and applied on aluminum may be safely used as food-contact coatings, in accordance with the following prescribed conditions:

(a) For the purpose of this section, partial phosphoric acid esters of polyester resins are prepared by the reaction of trimellitic anhydride with 2,2-dimethyl-1,3-propanediol followed by reaction of the resin thus produced with phosphoric acid anhydride to produce a resin having an acid number of 81 to 98 and a phosphorus content of 4.05 to 4.65 percent by weight.

(b) The coating is chemically bonded to the metal and cured at temperatures exceeding 450° F.

(c) The finished food-contact coating, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use, as determined from tables 1 and 2 of § 175.300(d), yields total extractives in each extracting solvent not to exceed 0.3 milligrams per square inch of food-contact surface, as determined by the methods described in § 175.300(e), and the coating yields 2,2-dimethyl-1,3-propanediol in each extracting solvent not to exceed 0.3 micrograms per square inch of food-contact surface. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

§ 175.270 Poly(vinyl fluoride) resins.

Poly(vinyl fluoride) resins identified in this section may be safely used as components of food-contact coatings for containers having a capacity of not less than 5 gallons, subject to the provisions of this section.

(a) For the purpose of this section, poly(vinyl fluoride) resins consist of basic resins produced by the polymerization of vinyl fluoride.

(b) The poly(vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(1) *Solvent. N,N*-Dimethylacetamide, technical grade.

(2) *Solution.* Powdered resin and solvent are heated at 120° C until the resin is dissolved.

(3) *Temperature.* Flow times of the solvent and solution are determined at 110° C.

(4) *Viscometer.* Cannon-Ubbelohde size 50 semimicro dilution viscometer (or equivalent).

(5) *Calculation.* The calculation method used is that described in appendix X 1.3 (ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference; see paragraph (b) of this section for availability of the incorporation by reference) with the reduced viscosity determined for three concen-

tration levels not greater than 0.5 gram per deciliter and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

Reduced viscosity in terms of deciliters per gram =

$$\frac{t - to}{to \times c}$$

Where:

t=Solution efflux time.
to=Solvent efflux time.
c=Concentration of solution in terms of grams per deciliter.

[42 FR 14534, Mar. 15, 1977, as amended at 47 FR 11839, Mar. 19, 1982; 49 FR 10107, Mar. 19, 1984]

§ 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between the food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymerized substances.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and polymeric coatings that is the subject of a regulation in Subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b)(3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.
Candlenut.
Castor (including dehydrated).
Chinawood (tung).
Coconut.
Corn.
Cottonseed.
Fish (refined).
Hempseed.
Linseed.
Oiticica.
Perilla.
Poppyseed.
Pumpkinseed.
Safflower.
Sesame.
Soybean.
Sunflower.
Tall oil.
Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction, or modified by combination with maleic anhydride.

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in paragraph (b)(3)(i) of this section to form esters with:

Butylene glycol.
Ethylene glycol.
Pentaerythritol.
Polyethylene glycol.
Polypropylene glycol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(iii) Synthetic drying oils, as the basic polymer:

Butadiene and methylstyrene copolymer.
Butadiene and styrene copolymer, blown or unblown.
Maleic anhydride adduct of butadiene styrene.
Polybutadiene.

(iv) Natural fossil resins, as the basic resin:

Copal.
Damar.
Elemi.
Gilsonite.
Glycerol ester of damar, copal, elemi, and sandarac.
Sandarac.
Shellac.
Utah coal resin.

(v) Rosins and rosin derivatives, with or without modification by polymerization, isomerization, incidental decarboxylation, and/or hydrogenation, as follows:

(*a*) Rosins, refined to color grade of K or paler:

Gum rosin.
Tall oil rosin.
Wood rosin.

(*b*) Rosin esters formed by reacting rosin (paragraph (b)(3) (v)(*a*) of this section) with:

4,4′-*sec*-Butylidenediphenol-epichlorohydrin (epoxy).
Diethylene glycol.
Ethylene glycol.
Glycerol.
4,4′-Isopropylidenediphenol-epichlorohydrin (epoxy).
Methyl alcohol.
Pentaerythritol.

(*c*) Rosin esters (paragraph (b)(3) (v)(*b*) of this section) modified by reaction with:

Maleic anhydride.
o-, *m*-, and *p*-substituted phenol-formaldehydes listed in paragraph (b)(3)(vi) of this section.
Phenol-formaldehyde.

(*d*) Rosin salts:

Calcium resinate (limed rosin).
Zinc resinate.

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(*a*) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols.
p-*tert*-Amylphenol.
4,4′-*sec*-Butylidenediphenol.
p-*tert*-Butylphenol.
o-, *m*-, and *p*-Cresol.
p-Cyclohexylphenol.
4,4′-Isopropylidenediphenol.
p-Nonylphenol.
p-Octylphenol.
3-Pentadecyl phenol mixture obtained from cashew nut shell liquid.
Phenol.
Phenyl *o*-cresol.
p-Phenylphenol.
Xylenol.

(*b*) Adjunct for phenolic resins: Aluminum butylate.

(vii) Polyester resins (including alkyd-type), as the basic polymers, formed as esters of acids listed in paragraph (b)(3)(vii) (*a*) and (*b*) of this section by reaction with alcohols in paragraph (b)(3) (vii) (*c*) and (*d*) of this section.

(*a*) Polybasic acids:

Adipic.
Dimerized fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.
Fumaric.
Isophthalic.
Maleic.
Orthophthalic.
Sebacic.
Terephthalic.
Terpene-maleic acid adduct.
Trimellitic.

(*b*) Monobasic acids:

Benzoic acid.
4,4-Bis(4′-hydroxyphenyl)-pentanoic acid.
tert-Butyl benzoic acid.
Fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.
Rosins listed in paragraph (b)(3)(v)(*a*) of this section, for use only as reactants in oil-based or fatty acid-based alkyd resins.

(*c*) Polyhydric alcohols:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol for use only in forming polyester resins for coatings intended for use in contact with non-alcoholic foods.
Ethylene glycol.
Glycerol.
Mannitol.
α-Methyl glucoside.
Pentaerythritol.
Propylene glycol.
Sorbitol.
Triethylene glycol, for use as a component in polyester resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.
Trimethylol ethane.

Trimethylol propane.

(*d*) Monohydric alcohols:

Cetyl alcohol.
Decyl alcohol.
Lauryl alcohol.
Myristyl alcohol.
Octyl alcohol.
Stearyl alcohol.

(viii) Epoxy resins, catalysts, and adjuncts:

(*a*) Epoxy resins, as the basic polymer:

(Alkoxy C_{10}-C_{16})-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C_{10} carbon atoms and a minimum of 48 percent C_{12} carbon atoms and a minimum of 18 percent C_{14} carbon atoms, for use only in coatings that are intended for contact with dry bulk foods at room temperature.

4,4′-*sec*-Butylidenediphenol-epichlorohydrin.

4,4′-*sec*-Butylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4′-*sec*-Butylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:
  Allyl ether of mono-, di-, or trimethylol phenol.
  4,4′-*sec*-Butylidenediphenol-formaldehyde.
  4,4′-Isopropylidenediphenol-formaldehyde.
  Melamine-formaldehyde.
  Phenol-formaldehyde.
  Urea-formaldehyde.

Epoxidized polybutadiene.

Glycidyl ethers formed by reacting phenol-novolak resins with epichlorohydrin.

4,4′-Isopropylidenediphenol-epichlorohydrin.

4,4′-Isopropylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4′-Isopropylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:
  Allyl ether of mono-, di-, or trimethylol phenol.
  4,4′-*sec*-Butylidenediphenol-formaldehyde.
  4,4′-Isopropylidenediphenol-formaldehyde.
  Melamine-formaldehyde.
  Phenol-formaldehyde.
  Urea-formaldehyde.

(*b*) Catalysts and cross-linking agents for epoxy resins:

3-(Aminomethyl)-3,5,5-trimethylcyclohexylamine reacted with phenol and formaldehyde in a ratio of 2.6:1.0:2.0, for use only in coatings intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, Table 1, under Category I and Category VIII, at temperatures not exceeding 88° C (190° F).

Cyanoguanidine.

Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Diethylenetriamine.

Diphenylamine.

Ethylenediamine.

Isophthalyl dihydrazide for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

4,4′-Methylenedianiline, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

N-Oleyl-1,3-propanediamine with not more than 10 percent by weight of diethylaminoethanol.

Polyamine produced when 1 mole of the chlorohydrin diether of polyethylene glycol 400 is made to react under dehydrohalogenating conditions with 2 moles of *N*-octadecyltrimethylenediamine for use only in coatings that are subject to the provisions of paragraph (c) (3) or (4) of this section and that contact food at temperatures not to exceed room temperature.

Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Stannous 2-ethylhexanoate for use only as a catalyst at a level not to exceed 1 percent by weight of the resin used in coatings that are intended for contact with food under conditions of use D, E, F, and G described in Table 2 of paragraph (d) of this section.

Styrene oxide, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Tetraethylenepentamine.

Tetraethylenepentamine reacted with equimolar quantities of fatty acids.

Tri(dimethylaminomethyl) phenol and its salts prepared from the fatty acid moieties of the salts listed in paragraph (b)(3)(xxii)(*b*) of this section, for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

Triethylenetetramine.

Trimellitic anhydride (CAS Reg. No. 552-30-7) for use only as a cross-linking agent at a level not to exceed 15 percent by weight of the resin in contact with food under all conditions of use, except that resins intended for use with foods containing more than 8 percent alcohol must contact such food only under conditions of use D, E, F, and G described in Table 2 of paragraph (d) of this section.

Trimellitic anhydride adducts of ethylene glycol and glycerol, prepared by the reaction of 1 mole of trimellitic anhydride with 0.4–0.6 mole of ethylene glycol and 0.04–0.12 mole of glycerol, for use only as a cross-linking agent at a level not to exceed 10 percent by weight of the cured coating, provided that the cured coating only contacts food containing not more than 8 percent alcohol.

(*c*) Adjuncts for epoxy resins:

Aluminum butylate.

Benzoic acid, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in Table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Polyamides from dimerized vegetable oils and the amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section, as the basic polymer.

Silane coupled silica, prepared from the reaction of microcrystalline quartz with *N-beta*-(*N*-vinylbenzylamino) ethyl-*gamma*-aminopropyltrimethoxy silane, monohydrogen chloride, for use only in coatings intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, Table 1, under Category I and Category VIII, at temperatures not exceeding 88° C (190° F).

Succinic anhydride, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch, and that are intended for contact under conditions of use D, E, F or G described in Table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

(ix) Coumarone-indene resin, as the basic polymer.

(x) Petroleum hydrocarbon resin (cyclopentadiene type), as the basic polymer.

(xi) Terpene resins, as the basic polymer, from one or more of the following:

Dipentene.

α-Pinene.

β-Pinene.

(xii) Urea-formaldehyde, resins and their curing catalyst:

(*a*) Urea-formaldehyde resins, as the basic polymer:

Urea-formaldehyde.

Urea-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

Urea-formaldehyde chemically modified with one or more of the amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section.

(*b*) Curing (cross-linking) catalyst for urea-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiii) Triazine-formaldehyde resins and their curing catalyst:

(*a*) Triazine-formaldehyde resins, as the basic polymer:

Benzoguanamine-formaldehyde.

Melamine-formaldehyde.

Melamine-formaldehyde chemically modified with one or more of the following amine catalysts:

- Amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section.
- Dimethylamine-2-methyl-1-propanol.
- Methylpropanolamine.
- Triethanolamine.

Melamine-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

(*b*) Curing (cross-linking) catalyst for triazine-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiv) Modifiers (for oils and alkyds, including polyesters), as the basic polymer:

Butyl methacrylate.

Cyclopentadiene.

Methyl, ethyl, butyl, or octyl esters of acrylic acid.

Methyl methacrylate.

Styrene.

Vinyl toluene.

(xv) Vinyl resinous substance, as the basic polymers:

Polyvinyl acetate.

Polyvinyl alcohol.

Polyvinyl butyral.

Polyvinyl chloride.

Polyvinyl formal.

Polyvinylidene chloride.

Polyvinyl pyrrolidone.

Polyvinyl stearate.

Vinyl chloride-acetate-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.1 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer for use in coatings for containers.

Vinyl chloride-acetate, hydroxyl-modified copolymer.

Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.

Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed.

Vinyl chloride copolymerized with one or more of the following substances:
  Acrylonitrile.
  Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
  Maleic acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
  5-Norbornene-2,3-dicarboxylic acid, mono-*n*-butyl ester; for use such that the finished vinyl chloride copolymers contain not more than 4 weight percent of total polymer units derived from this comonomer.
  Vinyl acetate.
  Vinylidene chloride.

Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based on polymer solids for use only in coatings for containers intended for contact with foods under conditions B, C, D, E, F, G, or H described in Table 2 of paragraph (d) of this section.

(xvi) Cellulosics, as the basic polymer:

Carboxymethylcellulose.
Cellulose acetate.
Cellulose acetate-butyrate.
Cellulose acetate-propionate.
Ethylcellulose.
Ethyl hydroxyethylcellulose.
Hydroxyethylcellulose.
Hydroxypropyl methylcellulose.
Methylcellulose.
Nitrocellulose.

(xvii) Styrene polymers, as the basic polymer:

Polystyrene.
α-Methyl styrene polymer.
Styrene copolymerized with one or more of the following:
  Acrylonitrile.
  α-Methylstyrene.

(xviii) Polyethylene and its copolymers as the basic polymer:

Ethylene-ethyl acrylate copolymer.

Ethylene-isobutyl acrylate copolymers containing no more than 35 weight percent of total polymer units derived from isobutyl acrylate.

Ethylene-vinyl acetate copolymer.

Polyethylene.

(xix) Polypropylene as the basic polymer:

Polypropylene.

Maleic anhydride adduct of polypropylene The polypropylene used in the manufacture of the adduct complies with § 177.1520(c), item 1.1; and the adduct has a maximum combined maleic anhydride content of 0.8 percent and a minimum intrinsic viscosity of 0.9, determined at 135° C on a 0.1 percent solution of the modified polypropylene in decahydronaphthalene as determined by a method titled "Method for Determination of Intrinsic Viscosity of Maleic Anhydride Adduct of Polypropylene," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(xx) Acrylics and their copolymers, as the basic polymer:

Acrylamide with ethylacrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butanol.

Acrylic acid and the following esters thereof:
  Ethyl.
  Methyl.

Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates.

Butyl acrylate-styrene-methacrylic acid-hydroxypropyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxypropyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates and that are intended for contact, under condition of use D, E, F, or G described in Table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

Ethyl acrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(*a*) of this section.

Ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(*a*) of this section.

2-Ethylhexyl acrylate-ethyl acrylate copolymers prepared by copolymerization of 2-ethylhexyl acrylate and ethyl acrylate in a 7/3 weight ratio and having a number average molecular weight range of 5,800 to 6,500 and a refractive index, $n_D^{20^\circ}$ (40 percent in 2,2,4-trimethyl pentane) of 1.4130–1.4190; for use as a modifier for nylon resins complying with § 177.1500 of this chapter and for phenolic and epoxy resins listed in paragraph (b)(3) (vi) and (viii) of this section, respectively, at a level not to exceed 1.5 percent of the coating.

2-Ethylhexyl acrylate-methyl methacrylate-acrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii) of this section.

Methacrylic acid and the following esters thereof:
  Butyl.
  Ethyl.
  Methyl.

Methacrylic acid or its ethyl and methyl esters copolymerized with one or more of the following:
  Acrylic acid.
  Ethyl acrylate.
  Methyl acrylate.

n-Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 2 weight percent of total polymer units derived from methacrylic acid and containing no more than 9.5 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings in contact with dry food (food type VIII in Table 1 of paragraph (d) of this section). 2-(Dimethylamino) ethanol (C.A.S. Registry No. 108-01-0) may be employed as an optional adjuvant substance limited to no more than 2 weight percent based on polymer solids in the coating emulsion.

Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (M_n) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent. The polymers are for use only in contact with food of Types IV-A, V, VII in table 1 of paragraph (d) of this section, under use conditions E through G in table 2 of paragraph (d), and with food of Type VIII without use temperature restriction.

(xxi) Elastomers, as the basic polymer:

Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
Chlorinated rubber.
2-Chloro-1,3-butadiene (neoprene).
Natural rubber (natural latex or natural latex solids, smoked or unsmoked).
Polyisobutylene.
Rubber hydrochloride.
Styrene-isobutylene copolymer.

(xxii) Driers made by reaction of a metal from paragraph (b)(3)(xxii)(*a*) of this section with acid, to form the salt listed in paragraph (b)(3)(xxii)(*b*) of this section:

(*a*) Metals:

Aluminum.
Calcium.
Cerium.
Cobalt.
Iron.
Lithium.
Magnesium.
Manganese.
Zinc.
Zirconium.

(*b*) Salts:

Caprate.
Caprylate.
Isodecanoate.
Linoleate.
Naphthenate.
Neodecanoate.
Octoate (2-ethylhexoate).
Oleate.
Palmitate.
Resinate.
Ricinoleate.
Soyate.
Stearate.
Tallate.

(xxiii) Waxes:

Paraffin, Type I.
Paraffin, Type II.
Polyethylene.
Sperm oil.
Spermaceti.

(xxiv) Plasticizers:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
Butyl phthalyl butyl glycolate.
Butyl stearate.
p-tert-Butyl phenyl salicylate.
Dibutyl sebacate.
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate.
Epoxidized soybean oil (iodine number maximum 14; oxirane oxygen content 6% minimum), as the basic polymer.
Ethyl phthalyl ethyl glycolate.
2-Ethylhexyl diphenyl phosphate.
di-2-Ethylhexyl phthalate.
Glycerol.
Glyceryl monooleate.
Glyceryl triacetate.
Monoisopropyl citrate.
Propylene glycol.
Sorbitol.
Mono-, di-, and tristearyl citrate.
Triethyl citrate.
Triethylene glycol.
3-(2-Xenolyl)-1,2-epoxypropane.

(xxv) Release agents, as the basic polymer, when applicable:

N, N'-Dioleoylethylenediamine (CAS Reg. No. 110-31-6) for use only in ionomeric resins complying with § 177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with § 177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.
N,N'-Distearoyl ethylenediamine.
Linoleic acid amide.
Oleic acid amide.
Palmitic acid amide.
Petrolatum.
Polyethylene wax.
Polyoxyethylene glycol monooleate (mol. wt. of the polyoxyethylene glycol moiety greater than 300).
Polytetrafluoroethylene.
Silicones (not less than 300 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.
Silicones (not less than 100 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes limited to use only on metal substrates. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

(xxvi) Pigments and colorants:

Aluminum.
Aluminum hydrate.
Aluminum and potassium silicate (mica).
Aluminum mono-, di-, tristearate.
Aluminum silicate (China clay).
Barium sulfate.
Bentonite.
Bentonite, modified with dimethyl dioctadecyl ammonium ion.
Burnt umber.
Calcium carbonate.
Calcium silicate.
Calcium sulfate.
Carbon black (channel process).
Cobalt oxide-aluminum oxide.
Diatomaceous earth.
Iron oxides.
Magnesium oxide.
Magnesium silicate (talc).
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Raw sienna.
Silica.
Tartrazine lake (certified FD&C Yellow No. 5 only).
Titanium dioxide.
Titanium dioxide-barium sulfate.
Titanium dioxide-magnesium silicate.
Zinc carbonate.
Zinc oxide.

(xxvii) Surface lubricants:

Cottonseed oil and other edible oils.
Dibutyl sebacate.
Dioctyl sebacate.
Glyceryl monostearate.
Lanolin.
Mineral oil, white.
Palm oil.
Paraffin, Type I.
Paraffin, Type II.
Petrolatum.
Stearic acid.

(xxviii) Silicones and their curing catalysts:

(*a*) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

(*b*) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.
Stannous oleate.

Tetrabutyl titanate.

(xxix) Surface active agents:

Ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol (CAS Reg. No. 9014-85-1).

Poly[2-(diethylamino) ethyl methacrylate] phosphate (minimum intrinsic viscosity in water at 25° C is not less than 9.0 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to use at levels not to exceed 0.1 percent by weight of the copolymers.

Sodium dioctyl sulfosuccinate.

Sodium dodecylbenzenesulfonate

Sodium lauryl sulfate.

2,4,7,9-Tetramethyl-5-decyn-4,7-diol (C.A.S. Reg. No. 126-86-3), for use only in can coatings which are subsequently dried and cured at temperatures of at least 193° C (380° F) for 4 minutes.

(xxx) Antioxidants:

Butylated hydroxyanisole.

Butylated hydroxytoluene.

Gum guaiac.

Dilauryl thiodipropionate.

Nordihydroguaiaretic acid.

Propyl gallate.

Distearyl thiodipropionate.

Thiodipropionic acid.

2,4,5-Trihydroxybutyrophenone.

(xxxi) Can end cements (sealing compounds used for sealing can ends only): In addition to the substances listed in paragraph (b) of this section and those listed in § 177.1210(b)(5) of this chapter, the following may be used:

Butadiene-styrene-divinylbenzene copolymer (CAS Reg. No. 26471-45-4) for use only at levels not to exceed 23.8 percent by weight of the cement solids in can end cements.

Butadiene-styrene-fumaric acid copolymer.

4,4′-Butylidenebis (6-*tert*-butyl-*m*-cresol).

Dibenzamido phenyl disulfide.

Di-β-naphthyl phenylenediamine.

Dipentamethylene thiuram tetrasulfide.

Isobutylene-isoprene-divinylbenzene copolymers for use only at levels not to exceed 15 percent by weight of the dry cement composition.

Naphthalene sulfonic acid-formaldehyde condensate, sodium salt, for use only at levels not to exceed 0.6 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium decylbenzene sulfonate.

Sodium nitrite for use only at levels not to exceed 0.3 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.

Sodium phenylphenate.

Styrene-maleic anhydride resin, partial methyl and butyl (*sec-* or *iso-*) esters, for use only at levels not in excess of 3 percent of the cement solids in can end cement formulations.

Tetrasodium EDTA (tetrasodium ethylenediaminetetraacetate).

Tri (mixed mono- and dinonylphenyl) phosphite.

Zinc dibutyldithiocarbamate.

(xxxii) Side seam cements: In addition to the substances listed in paragraph (b)(3) (i) to (xxx), inclusive, of this section, the following may be used.

p-tert-Butyl perbenzoate as a catalyst for epoxy resin.

epsilon-Caprolactam-(ethylene-ethyl acrylate) graft polymer.

Dicumyl peroxide for use only as polymerization catalyst.

Diisodecyl phthalate for use only as plasticizer in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, Table 1, under Categories I, II, and VI.

4,4′-Bis(*alpha,alpha*-dimethylbenzyl)diphenylamine, CAS Reg. No. 10081-67-1.

Ethyl toluene sulfonamide.

N,N′-Hexamethylenebis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamide), CAS Reg. No. 23128-74-7.

Polyamides consisting of the following:

- Copolymer of *omega*-laurolactam and *espilon*-caprolactam, CAS Reg. No. 25191-04-2 (Nylon 12/6).
- Homopolymer of *omega*-aminododecanoic acid, CAS Reg. No. 24937-16-4.
- Homopolymer of *omega*-laurolactam, CAS Reg. No. 25038-74-8 (Nylon 12).

Polyamides derived from the following acids and amines:

- Acids:
  - Adipic.
  - Azelaic.

  - Sebacic.
  - Vegetable oil acids (with or without dimerization).
- Amines:
  - Diethylenetriamine.
  - Diphenylamine.
  - Ethylenediamine.
  - Hexamethylenediamine.
  - Tetraethylenepentamine.
  - Triethylenetetramine.
- Polypropylene glycol CAS Reg. No. 25322-69-4.
- Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.
- Tetrakis [methylene(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)]methane, CAS Reg. No. 6683-19-8.
- Toluene sulfonamide formaldehyde resin (basic polymer).
- Triethylene glycol methacrylate for use only as polymerization cross-linking agent in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, Table 1, under Categories I, II, and VI.
- Urea.

(xxxiii) Miscellaneous materials:

- Ammonium citrate.
- Ammonium potassium phosphate.
- Calcium acetate.
- Calcium ethyl acetoacetate.
- Calcium glycerophosphate.
- Calcium, sodium, and potassium oleates.
- Calcium, sodium, and potassium ricinoleates.
- Calcium, sodium, and potassium stearates.
- Castor oil, hydrogenated.
- Castor oil, sulfated, sodium salt (CAS Reg. No. 8002-33-3), for use only in coatings for containers intended for repeated use.
- Cetyl alcohol.
- Cyclohexanone-formaldehyde resin produced when 1 mole of cyclohexanone is made to react with 1.65 moles of formaldehyde such that the finished resin has an average molecular weight of 600-610 as determined by ASTM method D2503-82, "Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. For use only in contact with nonalcoholic and nonfatty foods under conditions of use E, F, and G, described in Table 2 of paragraph (d) this section.
- Decyl alcohol.
- Disodium hydrogen phosphate.
- Ethyl acetoacetate.
- Lauryl alcohol.
- Lecithin.
- Magnesium, sodium, and potassium citrate.
- Magnesium glycerophosphate.
- Magnesium stearate.
- Mono-, di-, and tricalcium phosphate.
- Monodibutylamine pyrophosphate as sequestrant for iron.
- Mono-, di-, and trimagnesium phosphate.
- Myristyl alcohol.
- Octyl alcohol.
- Phosphoric acid.
- Polybutene, hydrogenated; complying with the identity and limitations prescribed by § 178.3740 of this chapter.
- Poly(ethylene oxide).
- Sodium pyrophosphate.
- Stannous chloride.
- Stannous stearate.
- Stannous sulfate.
- Stearyl alcohol.
- 2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on metal under conditions of use E, F, and G described in Table 2 of paragraph (d) of this section, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.
- Tetrasodium pyrophosphate.
- Tridecyl alcohol produced from tetrapropylene by the oxo process, for use only as a processing aid in polyvinyl chloride resins.
- Vinyl acetate-dibutyl maleate copolymers produced when vinyl acetate and dibutyl maleate are copolymerized with or without one of the monomers: Acrylic acid or glycidyl methacrylate. For use only in coatings for metal foil used in contact with foods that are dry solids with the surface containing no free fat or oil. The finished copolymers shall contain at least 50 weight-percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight-percent of total polymer units derived from acrylic acid or glycidyl methacrylate.

(xxxiv) Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine, as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature.

(xxxv) Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.

(xxxvi) Methacrylonitrile grafted polybutadiene copolymers containing no more than 41 weight percent of total polymer units derived from methacrylonitrile; for use only in coatings that are intended for contact, under conditions of use D, E, F, or G described in Table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of paragraph (d) of this section, shall yield chloroform-soluble extractives, corrected for zinc extractives as zinc oleate, not to exceed the following:

(1) From a coating intended for or employed as a component of a container not to exceed 1 gallon and intended for one-time use, not to exceed 0.5 milligram per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container, in milligrams, divided by the area of the food-contact surface of the container in square inches. From a fabricated container conforming with the description in this paragraph (c)(1), the extractives shall not exceed 0.5 milligram per square inch of food-contact surface nor exceed 50 parts per million of the water capacity of the container as determined by the methods provided in paragraph (e) of this section.

(2) From a coating intended for or employed as a component of a container having a capacity in excess of 1 gallon and intended for one-time use, not to exceed 1.8 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(3) From a coating intended for or employed as a component of a container for repeated use, not to exceed 18 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(4) From coating intended for repeated use, and employed other than as a component of a container, not to exceed 18 milligrams per square inch of coated surface.

(d) Tables:

TABLE 1—TYPES OF FOOD

I. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
II. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high fat content.
IV. Dairy products and modifications:
  A. Water-in-oil emulsion, high or low fat.
  B. Oil-in-water emulsion, high or low fat.
V. Low moisture fats and oils.
VI. Beverages:
  A. Containing alcohol.
  B. Nonalcoholic.
VII. Bakery products.
VIII. Dry solids (no end test required).

TABLE 2—TEST PROCEDURES FOR DETERMINING THE AMOUNT OF EXTRACTIVES FROM RESINOUS OR POLYMERIC COATINGS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Condition of use	Types of food (see table 1)	Extractant		
		Water (time and temperature)	Heptane[1,2] (time and temperature)	8 percent alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212° F).	I, IV-B	250° F, 2 hr		
	III, IV-A, VII	do	150° F, 2 hr	

TABLE 2—TEST PROCEDURES FOR DETERMINING THE AMOUNT OF EXTRACTIVES FROM RESINOUS OR POLYMERIC COATINGS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES—Continued

Condition of use	Types of food (see table 1)	Extractant		
		Water (time and temperature)	Heptane [1] [2] (time and temperature)	8 percent alcohol (time and temperature)
B. Boiling water sterilized	II	212° F, 30 min		
	III, VII	do	120° F, 30 min	
C. Hot filled or pasteurized above 150° F.	II, IV-B	Fill boiling, cool to 100° F.		
	III, IV-A	do	120° F., 15 min	
	V		do	
D. Hot filled or pasteurized below 150° F.	II, IV-B, VI-B	150° F. 2 hr		
	III, IV-A	do	100° F. 30 min	
	V		do	
	VI-A			150° F. 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container).	I, II, IV-B, VI-B	120° F. 24 hr		
	III, IV-A	do	70° F, 30 min	
	V, VII		do	
	VI-A			120° F, 24 hr.
F. Refrigerated storage, no thermal treatment in the container).	I, II, III, IV-A, IV-B, VI-B, VII.	70° F, 48 hr		
	VI-A			70° F, 48 hr.
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII	70° F, 24 hr		
H. Frozen storage: Ready-prepared foods intended to be reheated in container at time of use:				
1. Aqueous or oil in water emulsion of high or low fat.	I, II, IV-B	212° F, 30 min		
2. Aqueous, high or low free oil or fat.	III, IV-A, VII	do	120° F, 30 min	

[1] Heptane extractant not to be used on wax-lined containers.

[2] Heptane extractivity results must be divided by a factor of five in arriving at the extractivity for a food product.

(e) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food product (Table 1, paragraph (d) of this section) that is being packed commercially in the test container and the normal conditions of thermal treatment used in packaging the type of food involved. Using Table 2 (paragraph (d) of this section), select the food-simulating solvent or solvents (demineralized distilled water, heptane, and/or 8 percent ethyl alcohol) and the time-temperature exaggerations of the container-use conditions. Aqueous products (Types I, II, IV-B, and VI-B) require only a water-extractability test at the temperature and time conditions shown for the most severe "conditions of use." Aqueous products with free oil or fat, and water-oil emulsions (types III, IV-A, and VII) will require determinations of both water extractability and heptane extractability. Low-moisture fats and oils (type V with no free water) require only the heptane extractability. Alcoholic beverages (type VI-A) require only the 8 percent alcohol extractant. Having selected the appropriate extractant or extractants simulating various types of foods and beverages and the time-temperature exaggerations over normal use, follow the applicable extraction procedure. Adapt the procedure, when necessary, for containers having a capacity of over 1 gallon.

(2) *Selection of coated-container samples.* For consumer-sized containers up to 1 gallon, quadruplicate samples of representative containers (using for each replicate sample the number of containers nearest to an

area of 180 square inches) should be selected from the lot to be examined.

(3) *Cleaning procedure preliminary to determining the amount of extractables from coated containers.* Quadruplicate samples of representative containers should be selected from the lot to be examined and must be carefully rinsed to remove extraneous material prior to the actual extraction procedure. Soda fountain pressure-type hot water rinsing equipment, consisting in its simplest form of a ⅛-inch-¼-inch internal diameter metal tube attached to a hot water line and bent so as to direct a stream of water upward, may be used. Be sure hot water has reached a temperature of 190° F-200° F before starting to rinse the container. Invert the container over the top of the fountain and direct a strong stream of hot water against the bottom and all sides for 1 minute, drain, and allow to dry.

(4) *Exposure conditions*—(i) *Water (250° F for 2 hours), simulating high-temperature heat sterilization.* Fill the container within ¼-inch of the top with a measured volume of demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker. Add a small amount of demineralized distilled water to the pressure cooker, but do not allow the water to touch the bottom of the container. Close the cooker securely and start to heat over a suitable burner. When a steady stream of steam emerges from the vent, close the vent and allow the pressure to rise to 15 pounds per square inch (250° F) and continue to maintain this pressure for 2 hours. Slowly release the pressure, open the pressure cooker when the pressure reads zero, and composite the water of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ii) *Water (212° F for 30 minutes), simulating boiling water sterilization.* Fill the container within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iii) *Water (from boiling to 100° F), simulating hot fill or pasteurization above 150° F.* Fill the container within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Insert a thermometer in the water and allow the uncovered container to stand in a room at 70° F-85° F. When the temperature reads 100° F, composite the water from each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iv) *Water (150° F for 2 hours), simulating hot fill or pasteurization below 150° F.* Preheat demineralized distilled water to 150° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 150° F water and cover with clean aluminum foil. Place the test container in an oven maintained at 150° F. After 2 hours, remove the test container from the oven and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(v) *Water (120° F for 24 hours), simulating room temperature filling and storage.* Preheat demineralized distilled water to 120° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 120° F water and cover with clean aluminum foil. Place the test container in an incubator or oven maintained at 120° F. After 24 hours, remove the test container from the incubator and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vi) *Water (70° F for 48 hours), simulating refrigerated storage.* Bring demineralized distilled water to 70° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70° F water, and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 48 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vii) *Water (70° F for 24 hours), simulating frozen storage.* Bring demineralized distilled water to 70° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70° F water and cover with clean aluminum foil. Place the container in a suitable room maintained at 70° F. After 24 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(viii) *Water (212° F for 30 minutes), simulating frozen foods reheated in the container.* Fill the container to within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ix) *Heptane (150° F for 2 hours) simulating high-temperature heat sterilization for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 150° F. At the same time preheat a pressure cooker or equivalent to 150° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 150° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 150° F incubator. After 2 hours, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(x) *Heptane (120° F for 30 minutes), simulating boiling water sterilization of fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker or equivalent to 120° F in an incubator. This pressure cooker is to serve only as a vented container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xi) *Heptane (120° F for 15 minutes), simulating hot fill or pasteurization above 150° F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker or equivalent to 120° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 15 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xii) *Heptane (100° F for 30 minutes), simulating hot fill or pasteurization below 150° F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 100° F. At the same time, preheat a pressure cooker or equivalent to 100° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 100° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 100° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiii) *Heptane (70° F for 30 minutes), simulating room temperature filling and storage of fatty foods only.* Fill the test container within ¼-inch of the top with a measured volume of the 70° F heptane and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 30 minutes, composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiv) *Heptane (120° F for 30 minutes), simulating frozen fatty foods reheated in the container.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker to 120° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xv) *Alcohol—8 percent (150° F for 2 hours), simulating alcoholic beverages hot filled or pasteurized below 150° F.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 150° F in a clean Pyrex flask. Fill the test container with within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil and place in an oven maintained at 150° F. After 2 hours, remove the container from the oven and immediately composite the alcohol from each replicate in a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvi) *Alcohol—8 percent (120° F for 24 hours), simulating alcoholic beverages room-temperature filled and stored.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 120° F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol, cover the container with clean aluminum foil and place in an oven or incubator maintained at 120° F. After 24 hours, remove the container from the oven or incubator and immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvii) *Alcohol—8 percent (70° F for 48 hours), simulating alcoholic beverages in refrigerated storage.* Bring 8 percent (by volume) ethyl alcohol in demineralized distilled water to 70° F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 48 hours, immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

NOTE: The tests specified in paragraph (e)(4) (i) through (xvii) of this section are applicable to flexible packages consisting of coated metal contacting food, in which case the closure end is double-folded and clamped with metal spring clips by which the package can be suspended.

(5) *Determination of amount of extractives*—(i) *Total residues.* Evaporate the food-simulating solvents from paragraph (e)(4) (i) to (xvii), inclusive, of this section to about 100 milliliters in the Pyrex flask and transfer to a clean, tared platinum dish, washing the flask three times with the solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 212° F. Cool the platinum dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram (e). Calculate the extractives in milligrams per square inch and in parts per million for the particular size of container being tested and for the specific food-simulating solvent used.

(*a*) *Water and 8-percent alcohol.*

Milligrams extractives per square inch =

$$\frac{e}{s}$$

Extractives residue = Ex =

$$\frac{(e)(a)(1000)}{(c)(s)}$$

(*b*) *Heptane.*

Milligrams extractives per square inch =

$$\frac{e}{(s)(F)}$$

Extractives residue = Ex =

$$\frac{(e)(a)(1000)}{(c)(s)(F)}$$

Where:

Ex = Extractives residue in ppm for any container size.

e = Milligrams extractives per sample tested.

a = Total coated area, including closure in square inches.

c = Water capacity of container, in grams.

s = Surface of coated area tested, in square inches.

F = Five, the ratio of the amount of extractives removed from a coated container by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil from a container tested under exaggerated conditions of thermal sterilization and use.

e' = Chloroform-soluble extractives residue.

ee' = Zinc corrected chloroform-soluble extractive residue.

e' or ee' is substituted for e in the above equations when necessary.

If when calculated by the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section, the concentration of extractives residue (Ex) exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed to paragraph (e)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residue).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (*e*), in the platinum dish, obtained in paragraph (e)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper in a Pyrex funnel, collecting the filtrate in a clean, tared platinum dish. Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 212° F. Cool the platinum dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (*e'*). This *e'* is substituted for *e* in the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section. If the concentration of extractives (*Ex*) still exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed as follows to correct for zinc extractives ("C" enamels only): Ash the residue in the platinum dish by heating gently over a Meeker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the platinum dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (*e'*) to obtain the zinc-corrected chloroform-soluble extractives residue (*ee'*). This *ee'* is substituted for *e* in the formulas in paragraph (e)(5)(i) (*a*) and (*b*) of this section. To comply with the limitations in paragraph (c) of this section, the chloroform-soluble extractives residue (but after correction for the zinc extractives in case of "C" enamels) must not exceed 50 parts per million and must not exceed in milligrams per square inch the limitations for the particular article as prescribed in paragraph (c) of this section.

(f) *Equipment and reagent requirements*—(1) *Equipment.*

Rinsing equipment, soda fountain pressure-type hot water, consisting in simplest form of a ⅛-inch-¼-inch inside diameter metal tube attached to a hot water line delivering 190° F-200° F water and bent so as to direct a stream of water upward.

Pressure cooker, 21-quart capacity with pressure gage, safety release, and removable rack, 12.5 inches inside diameter × 11 inches inside height, 20 pounds per square inch safe operating pressure.

Oven, mechanical convection, range to include 120° F-212° F explosion-proof, inside dimensions (minimum), 19" × 19" × 19", constant temperature to ±2° F (water bath may be substituted).

Incubator, inside dimensions (minimum) 19" × 19" × 19" for use at 100° F±2° F explosion proof (water bath may be substituted).

Constant-temperature room or chamber 70° F±2° F minimum inside dimensions 19" × 19" × 19".

Hot plate, nonsparking (explosion proof), top 12" × 20", 2,500 watts, with temperature control.

Platinum dish, 100-milliliter capacity minimum.

All glass, Pyrex or equivalent.

(2) *Reagents.*

Water, all water used in extraction procedure should be freshly demineralized (deionized) distilled water.

Heptane, reagent grade, freshly redistilled before use, using only material boiling at 208° F.

Alcohol, 8 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized or distilled water.

Chloroform, reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

Filter paper, Whatman No. 41 or equivalent.

(g) In accordance with good manufacturing practice, finished coatings intended for repeated food-contact use shall be thoroughly cleansed prior to their first use in contact with food.

(h) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977]

Editorial Note: For additional Federal Register citations affecting § 175.300, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 175.320 Resinous and polymeric coatings for polyolefin films.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from one or more of the basic olefin polymers complying with § 177.1520 of this chapter. The base polyolefin film may contain optional adjuvant substances permitted for use in polyolefin film by applicable regulations in Parts 170 through 189 of this chapter.

(b) The coatings are formulated from optional substances which are:

(1) Substances generally recognized as safe for use in or on food.

(2) Substances the use of which is permitted under applicable regulations in Parts 170 through 189 of this chapter, by prior sanctions, or approvals.

(3) Substances identified in this paragraph (b)(3) and subject to such limitations as are provided:

List of substances	Limitations
(i) Resins and polymers:	
Acrylic acid polymer and its ethyl or methyl esters	
Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, and the copolymer subsequently reacted with formaldehyde and butanol.	
Butadiene-acrylonitrile copolymer	
Butadiene-acrylonitrile-styrene terpolymer	
Butyl rubber	
N,N'-Diphenyl-*p*-phenylenediamine	For use only as a polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
2-Ethylhexyl acrylate copolymerized with one or more of the following:	
Acrylonitrile	
Itaconic acid	
Methacrylonitrile	
Methyl acrylate	
Methyl methacrylate	
4,4'-Isopropylidenediphenolepichlorohydrin average molecular weight 900.	
Melamine-formaldehyde as the basic polymer or chemically modified with methyl alcohol.	
Methacrylic acid and its ethyl or methyl esters copolymerized with one or more of the following:	
Acrylic acid	
Ethyl acrylate	
Methyl acrylate	
α-Methyl styrene polymer	
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).	For use only in coatings that contact food under conditions of use D, E, F, or G described in Table 2 of § 176.170(c) of this chapter, provided that the concentration of α-methylstyrene-vinyltoluene copolymer resins in the finished food-contact coating does not exceed 1.0 milligram per square inch of food-contact surface.
Petroleum alicyclic hydrocarbon resins	As defined in § 176.170 of this chapter. Blended with butyl rubber for use as a component of coatings on polyolefin fabric for bulk packaging of raw fruits and vegetables and used at a level not to exceed 30 percent by weight of the total coating solids.
Polyamide resins (CAS Reg. No. 68139-70-8), as the basic resin, derived from:	For use only in coatings for polypropylene films that contact food at temperatures not to exceed room temperature.
Dimerized vegetable oil or tall oil acids containing not more than 20 percent of monomer acids.	
Azelaic acid (CAS Reg. No. 123-99-9) in an amount not to exceed 3.7 percent by weight of the polyamide resin.	
Ethylenediamine (CAS Reg. No. 107-15-3)	

List of substances	Limitations
Piperazine (CAS Reg. No. 110–85–0) in an amount not to exceed 6.4 percent by weight of the polyamide resin.	
Polyamide resins, derived from dimerized vegetable oil acids (containing not more than 20% of monomer acids) and ethylenediamine, as the basic resin.	For use only in coatings for polyolefin films that contact food at temperatures not to exceed room temperature.
Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acids (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin.	For use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.
Polyester resins formed by reaction of one or more of the following polybasic acids and monobasic acids with one or more of the following polyhydric alcohols:	
Polybasic acids:	
Adipic	
Azelaic	For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, Table 1, under Category VIII, and under conditions of use E, F, or G, described in Table 2 of § 176.170(c) of this chapter.
Dimerized fatty acids derived from:	
Animal, marine or vegetable fats and oils	
Tall oil	
Fumaric	
Isophthalic	
Maleic	
o-Phthalic	
Sebacic	
Terephthalic	
Trimellitic	
Monobasic acids:	
Fatty acids derived from:	
Animal, marine, or vegetable fats and oils	
Gum rosin	As defined in § 178.3870 of this chapter. For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, Table 1, under Category VIII, and under conditions of use E, F, or G described in Table 2 of § 176.170(c) of this chapter.
Tall oil	
Polyhydric alcohols:	
1,3-Butylene gylcol	
Diethylene glycol	
2,2-Dimethyl-1,3-propanediol	
Dipropylene glycol	
Ethylene glycol	
Glycerol	
Mannitol	
α-Methyl glucoside	
Pentaerythritol	
Propylene glycol	
Sorbitol	
Trimethylol ethane	
Trimethylol propane	
Polyethylenimine	For use only as a primer subcoat to anchor epoxy surface coatings to the base sheet.
Polystyrene	
Polyvinyl acetate	
Polyvinyl chloride	
Styrene copolymerized with one or more of the following:	
Acrylonitrile	
α-Methyl styrene	

List of substances	Limitations
Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (M_n) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent.	For use only in contact with foods of Types IV-A, V, and VII in table 1 of § 176.170(c) of this chapter, under use conditions E through G in table 2 of § 176.170(c), and with foods of Types VIII and IX without use temperature restriction.
Styrene-isobutylene copolymer	
Terpene resins consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.	
2-Sulfoethyl metacrylate, sodium salt Chemical Abstracts Service No. 1804-87-1].	For use only in copolymer coatings under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.
Vinyl chloride-acetate, hydroxyl-modified copolymer or maleic acid-modified copolymer.	
Vinyl chloride copolymerized with one or more of the following:	
Acrylonitrile	
Vinyl acetate	
Vinylidene chloride	
Vinylidene chloride copolymerized with one or more of the following:	
Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.	
Acrylonitrile	
Itaconic acid	
Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.	
Methacrylonitrile	
Vinyl chloride	
(ii) Plasticizers:	
Acetyl tributyl citrate	
Acetyl triethyl citrate	
Butyl phthalyl butyl glycolate	
Butyl stearate	
Dibutyl sebacate	
Diethyl phthalate	
2-Ethylhexyl diphenyl phosphate	
Ethyl phthalyl ethyl glycolate	
Glycerol monooleate	
Glycerol triacetate	
Triethyl citrate	
(iii) Adjuvants (release agents, waxes, and dispersants):	
Acetone	
Amides (unsubstituted) of fatty acids from vegetable or animal oils.	
n-Butyl acetate	
n-Butyl alcohol	
Candelilla wax	
Carnauba wax	
Ethyl acetate	
Fatty acids from vegetable or animal oils and their aluminum, ammonium, calcium, magnesium, and sodium salts.	
Hexane	
Methyl ethyl ketone	
N,N'-Dioleoylethylenediamine (CAS Reg. No. 110-31-6)	For use only in ionomeric resins complying with § 177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with § 177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.
Petroleum waxes conforming to specifications included in a regulation in Subchapter B of this chapter.	

List of substances	Limitations
Polyvinyl alcohol, minimum viscosity of 4% aqueous solution at 20° C of 4 centipoises and percent alcoholysis of 87-100.	For use only as a dispersing agent at levels not to exceed 6% of total coating weight in coatings for pol-yolefin films provided the finished polyolefin films contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types V, VIII, and IX.
Sodium dioctyl sulfosuccinate	
Sodium dodecylbenzenesulfonate	
Sodium lauryl sulfate	
Sorbitan and sorbitol esters of fatty acids from vegetable or animal oils.	
Spermaceti wax	
Tetrahydrofuran	
Toluene	

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface.

(d) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 43 FR 7206, Feb. 21, 1978; 45 FR 6541, Jan. 29, 1980; 47 FR 22512, May 25, 1982; 49 FR 36497, Sept. 18, 1984; 50 FR 47209, Nov. 15, 1985]

§ 175.350 Vinyl acetate/crotonic acid copolymer.

A copolymer of vinyl acetate and crotonic acid may be safely used as a coating or as a component of a coating which is the food-contact surface of polyolefin films intended for packaging food, subject to the provisions of this section.

(a) The copolymer may contain added optional substances to impart desired properties.

(b) The quantity of any optional substance does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitations further provided.

(c) Any optional substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178, and § 179.45 of this chapter conforms with any specifications in such regulation.

(d) Optional substances as provided in paragraph (a) of this section include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for uses with a copolymer of vinyl acetate and crotonic acid and used in accordance with such sanction or approval.

(3) Substances identified in this subparagraph and subject to such limitations as are provided:

List of substances	Limitations
Silica	
Japan wax	

(e) Copolymer of vinyl acetate and crotonic acid used as a coating or as a component of a coating conforming with the specifications of paragraph (e)(1) of this section are used as provided in paragraph (e)(2) of this section.

(1) *Specifications.* (i) The chloroform-soluble portion of the water extractives of the coated film obtained with distilled water at 120° F for 24 hours does not exceed 0.5 milligram per square inch of coated surface.

(ii) The chloroform-soluble portion of the *n*-heptane extractives of the coated film obtained with *n*-heptane at 70° F for 30 minutes does not exceed 0.5 milligram per square inch of coated surface.

(2) *Conditions of use.* The copolymer of vinyl acetate and crotonic acid is used as a coating or as a component of a coating for polyolefin films for packaging bakery products and confectionery.

§ 175.360 Vinylidene chloride copolymer coatings for nylon film.

Vinylidene chloride copolymer coatings identified in this section and applied on nylon film may be safely used as food-contact surfaces, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from nylon resins complying with § 177.1500 of this chapter.

(b) The coatings are prepared from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylic acid, acrylonitrile, ethyl acrylate, methacrylic acid, methyl acrylate, methyl methacrylate (CAS Reg. No. 80-62-6; maximum use level 6 weight percent) and 2-sulfoethyl methacrylate (CAS Reg. No. 10595-80-9; maximum use level 1 weight percent). The finished copolymers contain at least 50 weight percent of polymer units derived from vinylidene chloride. The finished coating produced from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with methyl methacrylate and/or 2-sulfoethyl methacrylate, or with methyl methacrylate and/or 2-sulfoethyl methacrylate together with one or more of the other monomers from this section, is restricted to use at or below room temperature.

(c) Optional adjuvant substances employed in the production of the coatings or added thereto to impart desired properties may include sodium dodecylbenzenesulfonate.

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface when tested by the methods described in § 176.170(d) of this chapter.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 43 FR 7206, Feb. 21, 1978; 45 FR 76998, Nov. 21, 1980; 47 FR 54430, Dec. 3, 1982]

§ 175.365 Vinylidene chloride copolymer coatings for polycarbonate film.

Vinylidene chloride copolymer coatings identified in this section and applied on polycarbonate film may be safely used as food-contact surfaces, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from polycarbonate resins complying with § 177.1580 of this chapter.

(b) The coatings are prepared from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with acrylonitrile, methyl acrylate, and acrylic acid. The finished copolymers contain at least 50 weight-percent of polymer units derived from vinyldene chloride.

(c) Optional adjuvant substances employed in the production of the coatings or added thereto to impart desired properties may include sodium dodecylbenzenesulfonate in addition to substances described in § 174.5(d) of this chapter.

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of coated surface as determined by the methods described in § 176.170(d) of this chapter. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisons of § 180.22 of this chapter.

§ 175.380 Xylene-formaldehyde resins condensed with 4,4′-isopropylidenediphenol-epichlorohydrin epoxy resins.

The resins identified in paragraph (a) of this section may be safely used as a food-contact coating for articles intended for use in contact with food, in accordance with the following prescribed conditions.

(a) The resins are produced by the condensation of xylene-formaldehyde resin and 4,4′-isopropylidenediphenol-epichlorohydrin epoxy resins, to which may have been added certain optional adjuvant substances required in the production of the resins or added to impart desired physical and technical properties. The optional adjuvant substances may include resins produced by the condensation of allyl ether of mono-, di-, or trimethylol phenol and capryl alcohol and also may include substances identified in § 175.300(b)(3), with the exception of paragraph (b)(3)(xxxi) and (xxxii) of that section.

(b) The resins identified in paragraph (a) of this section may be used as a food-contact coating for articles intended for contact at temperatures not to exceed 160° F with food of Types I, II, VI-A and B, and VIII described in Table 1 of § 176.170(c) of this chapter provided that the coating in the finished form in which it is to contact food meets the following extractives limitations when tested by the methods provided in § 175.300(e):

(1) The coating when extracted with distilled water at 180° F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(2) The coating when extracted with 8 percent (by volume) ethyl alcohol in distilled water at 160° F for 4 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(c) The resins identified in paragraph (a) of this section may be used as a food-contact coating for articles intended for contact at temperatures not to exceed room temperature with food of Type VI-C described in Table 1 of § 176.170(c) of this chapter provided the coating in the finished form in which it is to contact food meets the following extractives limitations when tested by the methods provided in § 175.300(e):

(1) The coating when extracted with distilled water at 180° F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(2) The coating when extracted with 50 percent (by volume) ethyl alcohol in distilled water at 180° F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch.

§ 175.390 Zinc-silicon dioxide matrix coatings.

Zinc-silicon dioxide matrix coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section;

(a) The coating is applied to a metal surface, cured, and washed with water to remove soluble substances.

(b) The coatings are formulated from optional substances which include:

(1) Substances generally recognized as safe.

(2) Substances for which safe conditions of use have been prescribed in § 175.300.

(3) Substances identified in paragraph (c) of this section, subject to the limitations prescribed.

(c) The optional substances permitted are as follows:

List of substances	Limitations
Ethylene glycol	As a solvent removed by water washing.
Iron oxide	
Lithium hydroxide	Removed by water washing.
Methyl orange	As an acid-base indicator.
Potassium dichromate	Removed by water washing.
Silica gel	
Sodium silicate	
Zinc, as particulate metal	

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under the conditions of its intended use as shown in Tables 1 and 2 of § 175.300(d) (using 20 percent alcohol as the solvent when the type of food contains approximately 20 percent alcohol) shall yield total extractives not to exceed those prescribed in § 175.300(c)(3); lithium extractives not to exceed 0.025 milligram per square inch of surface; and chromium extractives not to exceed 0.05 microgram per square inch of surface.

(e) The coatings are used as food-contact surfaces for bulk reusable containers intended for storing, handling, and transporting food.

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Paper and Paperboard

Sec.
176.110 Acrylamide-acrylic acid resins.
176.120 Alkyl ketene dimers.
176.130 Anti-offset substances.
176.150 Chelating agents used in the manufacture of paper and paperboard.
176.160 Chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine.
176.170 Components of paper and paperboard in contact with aqueous and fatty foods.
176.180 Components of paper and paperboard in contact with dry food.
176.200 Defoaming agents used in coatings.
176.210 Defoaming agents used in the manufacture of paper and paperboard.
176.230 3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.
176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.
176.260 Pulp from reclaimed fiber.
176.300 Slimicides.
176.320 Sodium nitrate-urea complex.
176.350 Tamarind seed kernel powder.

AUTHORITY: Secs. 201(s), 409, 72 Stat. 1784-1788, as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

SOURCE: 42 FR 14554, Mar. 15, 1977, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Paper and Paperboard

§ 176.110 Acrylamide-acrylic acid resins.

Acrylamide-acrylic acid resins may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Acrylamide-acrylic acid resins are produced by the polymerization of acrylamide with partial hydrolysis or by the copolymerization of acrylamide and acrylic acid.

(b) The acrylamide-acrylic acid resins contain less than 0.2 percent residual monomer.

(c) The resins are used as adjuvants in the manufacture of paper and paperboard in amounts not to exceed that necessary to accomplish the technical effect and not to exceed 2 percent by weight of the paper or paperboard.

§ 176.120 Alkyl ketene dimers.

Alkyl ketene dimers may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The alkyl ketene dimers are manufactured by the dehydrohalogenation of the acyl halides derived from the fatty acids of animal or vegetable fats and oils.

(b) The alkyl ketene dimers are used as an adjuvant in the manufacture of paper and paperboard under such conditions that the alkyl ketene dimers and their hydrolysis products dialkyl ketones do not exceed 0.4 percent by weight of the paper or paperboard.

(c) The alkyl ketene dimers may be used in the form of an aqueous emulsion which may contain sodium lignosulfonate as a dispersant.

§ 176.130 Anti-offset substances.

Substances named in paragraphs (b) and (c) of this section may be safely used to prevent the transfer of inks employed in printing and decorating paper and paperboard used for food packaging in accordance with the provisions of this section:

(a) The substances are applied to the nonfood contact, printed side of the paper or paperboard in an amount not greater than that required to accomplish the technical effect nor greater than any specific limitations, where such are provided.

(b) Anti-offset powders are prepared from substances that are generally recognized as safe in food, substances for which prior sanctions or approvals were granted and which are used in accordance with the specific provisions of such sanction or approval, and substances named in paragraph (c) of this section.

(c) The substances permitted are as follows:

Substances	Limitations
Carbon tetrachloride	
Methyl hydrogen polysiloxanes.	
Industrial starch—modified	Complying with § 178.3520 of this chapter.
Stannous oleate	
Zinc-2-ethyl hexoate	

§ 176.150 Chelating agents used in the manufacture of paper and paperboard.

The substances named in paragraph (a) of this section may be safely used in the manufacture of paper and paperboard, in accordance with the conditions prescribed in paragraphs (b) and (c) of this section:

(a) Chelating agents: 04

List of substances	Limitations
Ammonium fructoheptonate	
Ammonium glucoheptonate	
Disodium ethylenediamine tetraacetate.	
Pentasodium salt of diethylenetriamine pentaacetate.	
Sodium fructoheptonate	
Sodium glucoheptonate	
Tetrasodium ethylenediamine tetraacetate.	
Trisodium *N*-hydroxyethyl ethylenediamine triacetate.	

(b) Any one or any combination of the substances named is used or intended for use as chelating agents.

(c) The substances are added in an amount not greater than that required to accomplish the intended technical effect nor greater than any specific limitation, where such is provided.

§ 176.160 Chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine.

The chromium (Cr III) complex of *N*-ethyl - *N* - heptadecylfluoro-octane sulfonyl glycine containing up to 20 percent by weight of the chromium (Cr III) complex of heptadecylfluoro-octane sulfonic acid may be safely used as a component of paper for packaging dry food when used in accordance with the following prescribed conditions.

(a) The food additive is used as a component of paper in an amount not to exceed 0.5 percent by weight of the paper.

(b)(1) The food-contact surface of the paper is overcoated with a polymeric or resinous coating at least ⅓-mil in thickness, that meets the provision of § 176.170; or

(2) The treated paper forms one or more plies of a paper in a multiwall bag and is separated from the food by at least one ply of packaging films or grease-resistant papers which serves as a functional barrier between the food additive and the food. Such packaging films or grease-resistant papers conform with appropriate food additive regulations.

(c) The labeling of the food additive shall contain adequate directions for its use to insure compliance with the requirements of paragraphs (a) and (b) of this section.

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of Table 1 in paragraph (c) of this section are subject to the provisions of § 176.180.

(a) Substances identified in paragraph (a)(1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: *Provided*, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: *And provided further*, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this paragraph (a) are present in the food-contact surface of such paper or paperboard.

(1) Substances generally recognized as safe in food.

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in Parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this paragraph, as follows:

List of Substances	Limitations
Acetyl peroxide	For use only as polymerization catalyst.
Acrylamide-methacrylic acid-maleic anhydride copolymers containing not more than 0.2 percent of residual acrylamide monomer and having an average nitrogen content of 14.9 percent such that a 1 percent by weight aqueous solution has a minimum viscosity of 600 centipoises at 75° F, as determined by LVG-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 0.05 percent by weight of dry fibers in the finished paper and paperboard.
Acrylamide-β-methacrylyloxyethyltrimethylammonium methyl sulfate copolymer resins containing not more than 10 molar percent of β-methacrylyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide monomer.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Acrylonitrile polymer, reaction product with ethylenediamine sulfate having a nitrogen content of 22.5-25.0 percent (Kjeldahl dry basis) and containing no more than 0.075 percent monomer as ethylenediamine. The finished resin in a 24 percent by weight aqueous solution has a viscosity of 1,000-2,000 centipoises at 25° C as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 50 r.p.m. (or by other equivalent method).	For use only as a size promoter and retention aid at a level not to exceed 0.5 percent by weight of the dry paper and paperboard.
Acrylonitrile polymer with styrene, reaction product with ethylenediamine acetate, having a nitrogen content of 7.4-8.3 percent (Kjeldahl dry basis) and containing no more than 0.25 percent monomer as ethylenediamine.	1. For use only as a sizing material applied after the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 0.25 percent by weight of the dry paper and paperboard. 2. For use only as a sizing material applied prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 1.0 percent by weight of the dry paper and paperboard.
1-Alkenyl olefins, containing not less than 72 percent of C30 and higher olefins.	For use only under the following conditions: 1. In coatings for paper and paperboard with food of Types I, II, IV-B, and VII-B described in Table 1 of paragraph (c) of this section under conditions of use E, F, and G described in Table 2 of paragraph (c) of this section. 2. In coatings for paper and paperboard with food of Type VIII described in Table I of paragraph (c) of this section under conditions of use A through H described in Table 2 of paragraph (c) of this section.
(2-Alkenyl) succinic anhydrides mixture, in which the alkenyl groups are derived from olefins which contain not less than 95 percent of C_{15}-C_{21} groups.	For use only as a sizing agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished dry paper and paperboard fibers.
tert-Alkyl(C_8-C_{16})mercaptans	For use only as polymerization-control agent.

List of Substances	Limitations
Aluminum acetate	
Ammonium bis(*N*-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, containing not more than 15% ammonium mono (*N*-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, where the alkyl group is more than 95% C_8 and the salts have a fluorine content of 50.2% to 52.8% as determined on a solids basis.	For use only as an oil and water repellant at a level not to exceed 0.17 pound (0.09 pound of fluorine) per 1,000 square feet of treated paper or paperboard of a sheet basis weight of 100 pounds or less per 3,000 square feet of paper or paperboard, and at a level not to exceed 0.5 pound (0.26 pound of fluorine) per 1,000 square feet of treated paper or paperboard having a sheet basis weight greater than 100 lb. per 3,000 square feet as determined by analysis for total fluorine in the treated paper or paperboard without correction for any fluorine that might be present in the untreated paper or paperboard, when such paper or paperboard is used as follows: 1. In contact, under conditions of use C, D, E, F, G, or H described in Table 2 of paragraph (c) of this section, with nonalcoholic food. 2. In contact with bakery products of Type VII, VIII, and IX described in Table I of paragraph (c) of this section under good manufacturing practices of commercial and institutional baking.
Ammonium persulfate	
Ammonium thiosulfate	
Ammonium zirconium carbonate (CAS Reg. No. 32535-84-5) and its tartaric acid adduct.	For use only as an insolubilizer for binders used in coatings for paper and paperboard, and limited to use at a level not to exceed 2.5 percent by weight of coating solids.
9,10-Anthraquinone (Chemical Abstracts Service Registry No. 84-65-1) which has a purity of not less than 98 percent.	For use only as a pulping aid in the alkaline pulping of lignocellulosic material at levels not to exceed 0.1 percent by weight of the raw lignocellulosic material.
Azo-bisisobutyronitrile	For use only as polymerization catalyst.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5)	For use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.01 mg/in^2 (0.0016 mg/cm^2) of the finished paper and paperboard.
Benzoyl peroxide	Do.
N,N-Bis(2-hydroxyethyl)alkyl (C_{12}–C_{18})amide	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet forming operation.
Bis(methoxymethyl)tetrakis[(octadecyloxy)-methyl]melamine resins having a 5.8–6.5 percent nitrogen content.	For use only under the following conditions: 1. As a water repellant employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the finished paper and paperboard will contain the additive at a level not in excess of 1.6 percent by weight of the finished dry paper and paperboard fibers. 2. The finished paper and paperboard will be used in contact with nonalcoholic foods only.
tert-Butyl hydroperoxide	For use only as polymerization catalyst.
tert-Butyl peroxide	Do.
Calcium isostearate	For use only with *n*-decyl alcohol as a stabilizing material for aqueous calcium stearate dispersions intended for use as components of coatings for paper and paperboard.
Carrageenan and salts of carrageenan as described in §§ 172.620 and 172.626 of this chapter.	
Castor oil, hydrogenated	
Castor oil, sulfated, ammonium, potassium, or sodium salt	
Cellulose, regenerated	
Chloracetamide	For use only as polymerization-control agent.
Cobaltous acetate	For use only as polymerization catalyst.
Cumene hydroperoxide	Do.
Cyanoguanidine	For use only: 1. As a modifier for amino resins. 2. As a fluidizing agent in starch and protein coatings for paper and paperboard.
n-Decyl alcohol	For use only with calcium isostearate as a stabilizing material for aqueous calcium stearate dispersions intended for use as components of coatings for paper and paperboard.
Dialdehyde guar gum	For use only as a wet-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1% by weight of the finished dry paper and paperboard fibers.
Dialdehyde locust bean gum	Do.

List of Substances	Limitations
Dialkyl(C_{16}–C_{18})carbamoyl chloride (CAS Reg. No. 41319-54-4) manufactured by the reaction of secondary amines derived from fatty acids of animal or vegetable sources with phosgene.	For use as a sizing agent at a level not to exceed 0.2 percent by weight of the dry fiber.
Diallyldimethyl ammonium chloride polymer with acrylamide and potassium acrylate, produced by copolymerizing either (1) diallyldimethyl ammonium chloride and acrylamide in a weight ratio of 50/50, with 4.4 percent of the acrylamide subsequently hydrolyzed to potassium acrylate or (2) polymerized diallyldimethyl ammonium chloride, acrylamide and potassium acrylate (as acrylic acid) in a weight ratio of 50/47.8/2.2, respectively, so that the finished resin in a 1 percent by weight aqueous solution (active polymer) has a viscosity of more than 22 centipoises at 22° C (72° F) as determined by LVF series, Brookfield Viscometer using No. 1 spindle at 60 RPM (or by other equivalent method) (CAS Reg. No. 25136-75-8).	For use only as a retention and/or drainage aid employed prior to the sheet-forming operations in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.
Diallyldimethylammonium chloride with acrylamide (CAS Reg. No. 26590-05-6). The copolymer is produced by copolymerizing diallyldimethylammonium chloride with acrylamide in a weight ratio of 50-50 so that the finished resin in a 1 percent by weight aqueous solution (active polymer) has a viscosity of more than 22 centipoises at 22° C (71.6° F), as determined by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a drainage and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.
Diallyldiethylammonium chloride polymer with acrylamide, and diallyldimethylammonium chloride, produced by copolymerizing acrylamide, diallyldiethylammonium chloride, and diallyldimethylammonium chloride, respectively, in the following weight ratios and having viscosities determined at 22° C, by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method), as follows:	
1. Weight ratio: 50-2.5-47.5. The finished resin in a 1 percent by weight aqueous solution has a minimum viscosity of 22 centipoises.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished papor and paperboard.
2. Weight ratio: 25-2.5-72.5. The finished resin in a 0.20 percent by weight aqueous solution has a minimum viscosity of 20 centipoises.	For use only as a drainage and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.075 percent by weight of the finished paper and paperboard.
3. Weight ratio: 80-2.5-17.5. The finished resin in a 0.30 percent by weight aqueous solution has a minimum viscosity of 50 centipoises.	For use only as a drainage and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.075 percent by weight of the finished paper and paperboard.
Diallyldiethylammonium chloride polymer with acrylamide, potassium acrylate, and diallyldimethylammonium chloride. The polymer is produced by copolymerizing either: (1) acrylamide, diallyldiethylammonium chloride, and diallyldimethylammonium chloride in a weight ratio of 50-2.5-47.5, respectively, with 4.4 percent of the acrylamide subsequently hydrolyzed to potassium acrylate, or (2) acrylamide, potassium acrylate (as acrylic acid), diallyldiethylammonium chloride, and diallyldimethylammonium chloride in a weight ratio of 47.8-2.2-2.5-47.5, so that the finished resin in a 1 percent by weight aqueous solution has a minimum viscosity of 22 centipoises at 22° C, as determined by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.
Diallyldimethylammonium chloride polymer with acrylamide, reaction product with glyoxal, produced by copolymerizing not less than 90 weight percent of acrylamide and not more than 10 weight percent of diallyldimethylammonium chloride, which is then cross-linked with not more than 30 weight percent of glyoxal, such that a 10 percent aqueous solution has a minimum viscosity of 25 centipoises at 25° C as determined by Brookfield viscometer Model RVF, using a No. 1 spindle at 100 r.p.m.	For use only as a dry and wet strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 2 percent by weight of the dry fibers in the finished paper and paperboard.
2,5Di-*tert*-butyl hydroquinone	For use only as an antioxidant for fatty based coating adjuvants provided it is used at a level not to exceed 0.005% by weight of coating solids.

List of Substances	Limitations
Diethanolamine	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Diethanolamine salts of mono- and bis (1*H*,1*H*,2*H*,2*H*-perfluoroalkyl) phosphates where the alkyl group is even-numbered in the range C_8–C_{18} and the salts have a fluorine content of 52.4% to 54.4% as determined on a solids basis.	For use only as an oil and water repellant at a level not to exceed 0.17 pound (0.09 pound of fluorine) per 1,000 square feet of treated paper or paperboard, as determined by analysis for total fluorine in the treated paper or paperboard without correction for any fluorine which might be present in the untreated paper or paperboard, when such paper or paperboard is used in contact with nonalcoholic foods under the conditions of use described in paragraph (c) of this section, Table 2, conditions of use (B) through (H).
Diethyl(2-hydroxyethyl) methylammonium methyl sulfate, acrylate, polymer with acrylamide, chemical abstract service registry No. [26796–75–8] having 90–95 mole pct. acrylamide, a nitrogen content of not more than 19.7 pct. (Kjeldahl, dry basis), and a residual acrylamide monomer content of not more than 0.1 pct. The finished polymer in a 1 pct. by weight aqueous solution has a minimum viscosity of 900 centipoises at 25° C as determined by LVT-series Brookfield viscometer using a No. 2 spindle at 12 r.p.m. (or by equivalent method).	For use only as a retention aid and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.15 pct. by weight of finished dry paper and paperboard fibers.
Diethylenetriamine	For use only as a modifier for amino resins.
N,N-Diisopropanolamide of tallow fatty acids	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Dimethylamine-epichlorohydrin copolymer in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine and in which the ratio of total amine to epichlorohydrin does not exceed 1:1. The nitrogen content of the copolymer shall be 9.4 to 10.8 weight percent on a dry basis and a 10 percent by weight aqueous solution of the final product has a minimum viscosity of 5.0 centipoises at 25° C, as determined by LVT-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a retention aid employed before the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished paper and paperboard.
N-[(Dimethylamino)methyl]-acrylamide polymer with acrylamide and styrene having a nitrogen content of not more than 16.9 percent and a residual acrylamide monomer content of not more than 0.2 percent on a dry basis.	For use only as a dry-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of finished dry paper or paperboard fibers.
N,N'-Dioleoylethylenediamine	
Diphenylamine	For use only as an antioxidant for fatty based coating adjuvants provided it is used at a level not to exceed 0.005% by weight of coating solids.
Dipropylene glycol	
Disodium salt of 1,4-dihydro-9,10-dihydroxyanthracene (CAS Reg. No. 73347–80–5).	For use only as a catalyst in the alkaline pulping of lignocellulosic materials at levels not to exceed 0.1 percent by weight of the raw lignocellulosic materials.
N,N'-Distearoylethylenediamine	
n-Dodecylguanidine acetate	For use only as an antimicrobial agent in paper and paperboard under the following conditions: 1. For contact only with nonalcoholic food having a pH above 5 and provided it is used at a level not to exceed 0.4 percent by weight of the paper and paperboard. 2. For use in the outer ply of multiwall paper bags for contact with dry food of Type VIII described in Table I of paragraph (c) of this section and provided it is used at a level of 0.8 percent by weight of the paper.
n-Dodecylguanidine hydrochloride	For use only as an antimicrobial agent in paper and paperboard under the following conditions: 1. For contact only with nonalcoholic food having a pH above 5 and provided it is used at a level not to exceed 0.4 percent by weight of the paper and paperboard. 2. For use in the outer ply of multiwall paper bags for contact with dry food of Type VIII described in Table I of paragraph (c) of this section and provided it is used at a level of 0.8 percent by weight of the paper.
Fatty acids derived from animal and vegetable fats and oils and salts of such acids, single or mixed, as follows: Aluminum. Ammonium. Calcium.	

List of Substances	Limitations
Magnesium.	
Potassium.	
Sodium.	
Zinc.	
Ferric chloride	
Ferrous ammonium sulfate	
Fish oil, hydrogenated	
Fish oil, hydrogenated, potassium salt	
Furcelleran and salts of furcelleran as described in §§ 172.655 and 172.660 of this chapter.	
Glutaraldehyde (CAS Reg. No. 111-30-8)	For use only as an antimicrobial agent in pigment and filler slurries used in the manufacture of paper and paperboard at levels not to exceed 300 parts per million by weight of the slurry solids.
Glyceryl lactostearate	
Glyceryl mono-1,2-hydroxystearate	
Glyceryl monoricinoleate	
Guar gum modified by treatment with β-diethylamino- ethyl chloride hydrochloride.	For use only as a retention aid and/or drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Guar gum modified by treatment with not more than 25 weight percent of 2,3-epoxypropyltri-methylammonium chloride such that the finished product has a maximum chlorine content of 4.5 percent, a maximum nitrogen content of 3.0 percent, and a minimum viscosity in 1-percent-by-weight aqueous solution of 1,000 centipoises at 77° F, as determined by RV-series Brookfield viscometer (or equivalent) using a No. 3 spindle at 20 r.p.m.	For use only as a retention aid and/or internal size employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and limited to use at a level: (1) Not to exceed 0.15 percent by weight of the finished dry paper and paperboard fibers intended for use in contact with all types of foods, except (2) not to exceed 0.30 pct. by weight of the finished dried paper and paperboard fibers for use with nonalcoholic and nonfatty food of types identified under Types I, II, IV-B, VI-B, VII-B, and VIII of Table I in par. (c) of this section.
Hexamethylenetetramine	For use only as polymerization cross-linking agent for protein, including casein.
Hydroquinone and the monomethyl or monoethyl ethers of hydroquinone.	For use only as an inhibitor for monomers.
Hydroxypropyl guar gum having a minimum viscosity of 5,000 centipoises at 25° C., as determined by RV-series Brookfield viscometer using a No. 4 spindle at 20 r.p.m. (or other suitable method) and using a test sample prepared by dissolving 5 grams of moisture-free hydroxypropyl guar gum in 495 milliliters of a 70 percent by weight aqueous propylene glycol solution.	For use only as a dry strength and formation aid agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.5 percent by weight of finished dry paper or paperboard fibers.
Isopropyl *m*- and *p*-cresols (thymol derived)	For use only as an antioxidant for fatty based coating adjuvants provided it is used as a level not to exceed 0.005% by weight of coating solids.
Isopropyl peroxydicarbonate	For use only as polymerization catalyst.
Japan wax	
Lanolin	
Lauryl peroxide	For use only as polymerization catalyst.
Lauryl sulfate salts:	
Ammonium.	
Magnesium.	
Potassium.	
Sodium.	
Lecithin, hydroxylated	
Lignin sulfonate and its calcium, potassium, and sodium salts	
N-methyldiallylamine hydrochloride polymer with epichlorohydrin having a nitrogen content of 4.8 to 5.9 percent (Kjeldahl dry basis) such that a 20 percent by weight aqueous solution has a minimum viscosity of 30 centipoises and maximum viscosity of 100 centipoises at 25° C, as determined by LVF Model Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or equivalent method).	For use only as a retention aid, flocculating agent, and wet-strength agent employed in the manufacture of paper and paperboard prior to the sheet-forming operation and limited to use at a level not to exceed 1.5 percent by weight of the dry paper and paperboard.
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
N-methyl-*N*-(tall oil acyl) taurine, sodium salt (CAS Reg. No. 61791-41-1).	For use only to control scale formation in the manufacture of paper and paperboard prior to the sheetforming operation at a level not to exceed 0.015 percent by weight of the dry paper and paperboard.
Mineral oil, white	
Mono-, di-, tri-(1-methyl-1-phenylethyl)-phenol, ethoxylated, sulfated, ammonium salt with an average of 12 to 16 moles of ethylene oxide (CAS Reg. No. 68130-71-2).	For use only as an emulsifier for rosin based sizing at a level not to exceed 0.03 percent by weight of the finished dry paper and paperboard.

List of Substances	Limitations
Monoglyceride citrate	
Mustardseed oil, sulfated, ammonium, potassium, or sodium salt.	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Nitrocellulose, 10.9–12.2% nitrogen	
Oleic acid, sulfated, ammonium, potassium, or sodium salt	
N-Oleoyl-*N*′-stearoylethylenediamine	
Oxystearin	
Paraformaldehyde	For use only as setting agent for protein.
Pentanoic acid, 4,4-bis [(*gamma-omega*-perfluoro-C_{8-20}-alkyl)thio] derivatives, compounds with diethanolamine (CAS Reg. No. 71608–61–2).	For use only as an oil and water repellent and used at a level not to exceed 8 pounds per ton of the finished paper or paperboard when such paper or paperboard is used in contact with nonalcoholic foods under conditions of use E through H described in Table 2 of paragraph (c) of this section.
Perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265–81–1) containing 35 to 40 weight percent fluorine, produced by the copolymerization of ethanaminium, *N,N,N*-trimethyl-2-[(2-methyl-1-oxo-2-propenyl)-oxy]-, chloride; 2-propenoic acid, 2-methyl-, oxiranylmethyl ester; 2-propenoic acid, 2-ethoxyethyl ester; and 2-propenoic acid, 2[[(heptadecafluoro- octyl)sulfonyl] methyl amino]ethyl ester.	For use only as an oil and water repellent at a level not to exceed 0.5 percent by weight of the finished paper and paperboard in contact with nonalcoholic foods under conditions of use C, D, E, F, G, or H described in table 2 of paragraph (c) of this section.
Petrolatum	Complying with § 178.3700 of this chapter.
Petroleum asphalt, steam and vacuum refined to meet the following specifications: Softening point 88° C to 93° C, as determined by ASTM method D36–76, "Standard Test Method for Softening Point of Bitumen (Ring-and-Ball Apparatus);" penetration at 25° C not to exceed 0.3 mm, as determined by ASTM method D5–73 (Reapproved 1978), "Standard Test Method for Penetration of Bituminous Materials," which are incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408); and maximum weight loss not to exceed 3% when distilled to 371° C, nor to exceed an additional 1.1% when further distilled between 371° C and thermal decomposition.	For use only as a component of internal sizing of paper and paperboard intended for use in contact only with raw fruits, raw vegetables, and dry food of the type identified under Type VIII of Table 1 in paragraph (c) of this section, and provided that the asphalt is used at a level not to exceed 5% by weight of the finished dry paper and paperboard fibers.
Petroleum wax, synthetic	Complying with § 178.3720 of this chapter.
Phenothiazine	For use only as antioxidant in dry rosin size.
Phenyl acid phosphate	For use only as polymerization catalyst in melamine-formaldehyde modified alkyd coatings and limited to use at a level not to exceed 2% by weight of the coating solids.
Phenyl-*β*-naphthylamine	For use only as antioxidant in dry rosin size and limited to use at a level not to exceed 0.4% by weight of the dry rosin size.
Phosphonic acid esters and polyesters (and their sodium salts) of triethanolamine formed by the reaction of triethanolamine with polyphosphonic acid to produce a mixture of esters having an average nitrogen content of 1.5 percent and an average phosphorus content of 32 percent (as PO_4).	For use as an adjuvant prior to the sheet forming operation to control pitch and scale formation in the manufacture of paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, Table 1, under Types I, IV, V, VII, VIII, and IX, and used at a level not to exceed 0.075 percent by weight of dry paper or paperboard fibers.
Poly[acrylamide-acrylic acid-*N*-(dimethyl-aminomethyl)acrylamide], produced by reacting 2.40 to 3.12 parts by weight of polyacrylamide with 1.55 parts dimethylamine and 1 part formaldehyde, and containing no more than 0.2 percent monomer as acrylamide.	For use only as a drainage aid and retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard for use in contact with fatty foods under conditions of use described in paragraph (c) of this section, Table 2, conditions of use E, F, and G.
Poly(2-aminoethyl acrylate nitrate-*co*-2-hydroxypropyl acrylate) produced when one mole of hydroxypropyl acrylate and three moles of acrylic acid are reacted with three moles of ethylenimine and three moles of nitric acid, such that a 35 percent by weight aqueous solution has a minimum viscosity of 150 centipoises at 72° F., as determined by RVF-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 20 r.p.m.	For use only as a retention and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.2 percent by weight of dry paper or paperboard fiber.
Polyacrolein (1 part) -sodium bisulfite (3.7 part) adduct, containing excess bisulfite (ratio of excess bisulfite to adduct not to exceed 1.5 to 1).	For use only as an agent in modifying starches and starch gums used in the production of paper and paperboard and limited to use at a level not to exceed 0.09 mg/in² of the finished paper and paperboard.

List of Substances	Limitations
Poly[acrylamide-acrylic acid-*N*-(dimethylaminomethyl) acrylamide] (C.A. Registry No. 53800-41-2), produced by reacting 9.6-16.4 parts by weight of polyacrylamide with 1.6 parts dimethylamine and 1 part formaldehyde, and containing no more than 0.2% monomer as acrylamide, such that a 20% aqueous solution has a minimum viscosity of 4,000 cP at 25° C., as determined by Brookfield viscometer model RVT, using a No. 5 spindle at 20 r/min (or equivalent method).	For use only as a drainage aid, retention aid, or dry-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.25 percent by weight of finished dry paper and paperboard fibers, when such paper or paperboard is used in contact with fatty foods under conditions of use described in paragraph (c) of this section, Table 2, conditions of use E, F, and G.
Polyamide-epichlorohydrin modified resin produced by reacting adipic acid with diethylene triamine to produce a basic polyamide which is modified by reaction with formic acid and formaldehyde and further reacted with epichlorohydrin in the presence of ammonium hydroxide to form a water-soluble cationic resin having a nitrogen content of 13-16 percent (Kjeldahl, dry basis) such that a 35 percent by weight aqueous solution has a minimum viscosity of 75 centipoises at 25° C. as determined by Brookfield viscometer using a No. 1 spindle at 12 r.p.m.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 0.2 percent dry resin by weight of finished dry paper or paperboard fibers.
Polyamide-epichlorohydrin water-soluble thermosetting resins [CAS Reg. No. 68583-79-9] prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture such that the finished resins have a nitrogen content of 17.0 to 18.0 percent of a dry basis, and that a 30-percent-by-weight aqueous solution has a minimum viscosity of 350 centipoises at 20° C. as determined by a Brookfield viscometer using a No. 3 spindle at 30 r.p.m. (or equivalent method).	For use only under the following conditions: 1. As a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.12 percent by weight of dry paper or paperboard. 2. The finished paper or paperboard will be used in contact with food only of the types identified in paragraph (c) of this section, Table 1, under types I and IV-B and under conditions of use described in paragraph (c) of this section, Table 2, conditions of use F and G.
Polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid, isophthalic acid, itaconic acid or dimethyl glutarate with diethylenetriamine to form a basic polyamide and further reacting the polyamide with one of the following: Epichlorohydrin. Epichlorohydrin and ammonia mixture. Epichlorohydrin and sodium hydrosulfite mixture.	For use only in the manufacture of paper and paperboard under conditions such that the resins do not exceed 1.5 percent by weight of the paper or paperboard.
Polyamidol-epichlorohydrin modified resin produced by reacting glutaric acid dimethyl ester with diethylene-triamine to produce a basic polyamide which is modified by reaction with formaldehyde and further reacted with epicholorohydrin to form a water soluble cationic resin having a nitrogen content of 10.9-11.9 percent and a chlorine content of 13.8-14.8 percent, on a dry basis, and a minimum viscosity, in 12.5 percent by weight aqueous solution, of 10 centipoises at 25° C. as determined by a Brookfield Model LVF viscometer using a No. 1 spindle at 60 r.p.m. (or equivalent method).	For use only as a wet strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 2.5 percent by weight of dry paper and paperboard fibers when such paper or paperboard is used in contact with food under conditions of use E through G described in Table 2 of paragraph (c) of this section.
Polyamine-epichlorohydrin resin produced by the reaction of bis(hexamethylene)triamine and higher homologues with epichlorohydrin such that the finished resin has a nitrogen content of 6.3-8.9 percent and chlorine content of 18.0-26.3 percent on a dry basis, and a minimum viscosity in 20 percent by weight aqueous solution of 30 centipoises at 25° C. as determined by Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
Polyamine-epichlorohydrin resin produced by the reaction of epichlorohydrin with monomethylamine to form a prepolymer and further reaction of this prepolymer with *N,N,N',N'*-tetramethylethylenediamine such that the finished resin having a nitrogen content of 11.6 to 14.8 percent and a chlorine content of 20.8 to 26.4 percent and a minimum viscosity, in 25 percent by weight aqueous solution, of 500 centipoises at 25° C. as determined by LV-series Brookfield viscometer using a No. 2 spindle at 12 r.p.m. (or by other equivalent method).	For use only as a flocculant, drainage aid, formation aid, retention aid, or strength additive employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 0.12 percent by weight of dry paper and paperboard fibers.

List of Substances	Limitations
Polyamine-epichlorohydrin resin produced by the reaction of *N,N*-dimethyl-1,3-propanediamine with epichlorohydrin and further reacted with sulfuric acid, Chemical Abstracts Service Registry Number [27029–41–0], such that the finished resin has a maximum nitrogen content of 14.4 percent (dry basis) and a minimum viscosity in 30 percent by weight aqueous solution (pH 4–6) of 50 centipoises at 25° C, as determined by Brookfield LVT model viscometer, using a No. 1 spindle at 12 r.p.m. (or equivalent method).	For use only as a clarifier in the treatment of influent water to be used in the manufacture of paper and paperboard, and used at a level not to exceed 20 parts per million of the influent water.
Polyamine-epichlorohydrin water soluble thermosetting resin produced by reacting an aliphatic diamine mixture containing not less than 95 percent of C_4 to C_6 diamines with 1,2-dichloroethane to form a prepoler and further reacting this prepolymer with epichlorohydrin such that the finished resin has a nitrogen content of 6.6–7.9 percent and a chlorine content of 23.0–26.6 percent, on a dry basis, and a minimum viscosity, in 25 percent by weight aqueous solution, of 50 centipoises at 20° C, as determined on a Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheetforming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
Polyamine-epichlorohydrin water soluble thermosetting resin prepared by reacting hexamethylenediamine with 1,2-dichloroethane to form a prepolymer and further reacting this prepolymer with epichlorohydrin such that that finished resin has a nitrogen content of 5.2–5.5 percent and a chlorine content of 32.7–34.4 percent, on a dry basis, and a minimum viscosity, in 25 percent by weight aqueous solution, of 50 centipoises at 25° C., as determined on a Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
Polyamine-epichlorohydrin water soluble thermosetting resin prepared by reacting hexamethylenediamine with 1,2-dichloroethane to form a prepolymer and further reacting this prepolymer with epichlorohydrin. This resin is then reacted with nitrilotris (methylene-phosphonic acid), pentasodium salt, such that the finished resin has a nitrogen content of 5.0–5.3 percent; a chlorine content of 29.7–31.3 percent; and a phosphorus content of 2.0–2.2 percent, on a dry basis, and a minimum viscosity, in 25 percent by weight aqueous solution, of 50 centipoises at 25° C., as determined on a Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
Polyamine resin produced by the reaction of 1,2-dichloroethane with bis(hexamethylene)triamine and higher homologues such that the finished resin has a nitrogen content of 13.0–15.0 percent on a dry basis, and a minimum viscosity in 25-percent-by-weight aqueous solution of 75 centipoises at 25° C., as determined by Brookfield HAT model viscometer using a No. 1 spindle at 50 r.p.m. (or equivalent method).	For use only as a retention aid and/or flocculent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 0.1 percent by weight of dry paper or paperboard fibers.
Polyaminoamide-epichlorohydrin modified resin produced by reacting adipic acid with diethylenetriamine to produce a polyamide which is modified by reaction with diethylaminopropylamine and further reacted with dichloroethyl ether to form a polyamide intermediate. This polyamide intermediate is then reacted with epichlorohydrin such that the finished resins have a nitrogen content of 10.9–12.4 percent (Kjeldahl, dry basis) and a minimum viscosity in 40 percent-by-weight aqueous solution of 250 centipoises at 22° C, as determined by a Brookfield Model LVT viscometer using a No. 2 spindle at 30 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 0.5 percent by weight of the finished dry paper and paperboard.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.	For use only as provided in §§ 175.300, 178.3740 and 178.3860 of this chapter.
Poly(diallyldimethylammonium chloride) (CAS Reg. No. 26062–79–3) produced by the polymerization of diallyldimethylammonium chloride so that the finished resin has a nitrogen content of 8.66±0.4 percent on a dry weight basis and a minimum viscosity in a 40-weight percent aqueous solution of 1,000 centipoises at 25° C (77° F), determined by LVF Model Brookfield Viscometer using a No. 3 spindle at 30 r.p.m. (or equivalent method). The level of residual monomer is not to exceed 1 weight percent of the polymer (dry basis).	For use only as a pigment dispersant and/or retention aid prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 10 pounds of active polymer per ton of finished paper and paperboard.

List of Substances	Limitations
Poly(diallyldimethylammonium chloride) (CAS Reg. No. 26062-79-3) produced by the polymerization of diallyldimethylammonium chloride so that the finished resin has a nitrogen content of 8.66 ± 0.4 percent on a dry basis and a minimum viscosity in a 15--weight percent aqueous solution of 10 centipoises at 25° C (77° F), as determined by LVF Model Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or equivalent method). The level of residual monomer is not to exceed 1 weight percent of the polymer (dry basis).	For use only as a flocculant employed prior to sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 10 mg/L (10 parts per million) of influent water.
Poly(1,2-dimethyl-5-vinylpyridinium methyl sulfate) having a nitrogen content of 5.7 to 7.3 percent and a sulfur content of 11.7 to 13.3 percent by weight on a dry basis and having a minimum viscosity in 30-percent-by-weight aqueous solution of 2,000 centipoises at 25° C., as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 60 r.p.m.	For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation.
Polyester resin produced by reacting dimethylolpropionic acid (CAS Registry No. 4767-03-7) as a comonomer, at no more than 30 percent by weight of total polymer solids in reaction with 2,2-dimethyl-1,3-propanediol, phthalic anhydride and isophthalic acid, such that the polyester resin has a viscosity of 200-600 centipoises at 80° F as determined by a Brookfield RVT viscometer using a number 3 spindle at 50 rpm (or equivalent method).	For use only as a surface-sizing compound applied after the sheet-forming operation in the manufacture of paper and paperboard and limited to use at levels not to exceed 0.1 percent by weight of finished dry paper or paperboard.
Polyethylene, oxidized; complying with the identity prescribed in § 177.1620(a) of this chapter.	For use only as component of coatings that contact food only of the type identified under Type VII-B of Table 1 in paragraph (c) of this section, and limited to use at a level not to exceed 50 percent by weight of the coating solids.
Polyethyleneamine mixture produced when 1 mole of ethylene dichloride, 1.05 moles of ammonia, and 2 moles of sodium hydroxide are made to react so that a 10 percent aqueous solution has a minimum viscosity of 40 centipoises at 77° F, as determined by Brookfield viscometer using a No. 1 spindle at 60 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Polyethylene glycol (200) dilaurate	For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation.
Polyethylene glycol (400) dioleate	
Polyethylene glycol (400) esters of coconut oil fatty acids	
Polyethylene glycol (600) esters of tall oil fatty acids	
Polyethylene glycol (400) monolaurate	
Polyethylene glycol (600) monolaurate	
Polyethylene glycol (400) monooleate	
Polyethylene glycol (600) monooleate	
Polyethylene glycol (400) monostearate	
Polyethylene glycol (600) monostearate	
Polyethylene glycol (3,000) monostearate	
Polyethylenimine, produced by the polymerization of ethylenimine.	For use only as an adjuvant employed prior to sheet formation in paper-making systems operated at a pH of 4.5 or higher, and limited to use at a level not to exceed 5% by weight of finished dry paper or paperboard fibers.
Polymethacrylic acid, sodium salt, having a viscosity in 30-percent-by-weight aqueous solution of 125-325 centipoises at 25° C as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 60 r.p.m.	For use only as a coating adjuvant for controlling viscosity when used at a level not to exceed 0.3% by weight of coating solids.
Polymethacrylic acid, sodium salt, having a viscosity in 40-percent-by-weight aqueous solution of 400-700 centipoises at 25° C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a coating adjuvant for controlling viscosity when used at a level not to exceed 0.1% by weight of coating solids.
Poly[(methylimino)(2-hydroxytrimethylene)hydrochloride] produced by reaction of 1:1 molar ratio of methylamine and epichlorohydrin so that a 31-percent aqueous solution at 25° C has a Stokes viscosity range of 2.5-4.0 as determined by ASTM method D1545-76 (Reapproved 1981), "Standard Test Method for Viscosity of Transparent Liquids by Bubble Time Method," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	For use only as a retention aid employed prior to the sheet-forming operation in such an amount that finished paper and paperboard will contain the additive at a level not in excess of 1 percent by weight of the dry paper and paperboard.

List of Substances	Limitations
Poly[oxyethylene (dimethyliminio) ethylene (dimethyliminio) ethylene dichloride] produced by reacting equimolar quantities of *N,N,N,N*-tetramethylethylene-diamine and dichlorethyl ether to yield a solution of the solid polymer in distilled water at 25° C with a reduced viscosity of not less than 0.15 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for ·Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408). The following formula is used for determining reduced viscosity:. Reduced viscosity in terms of deciliters per gram $=(t-t_o)/(t-C)$, where: t = Solution efflux time t_o = Water efflux time C = Concentration of solution in terms of grams per deciliter	For use only to improve dry-strength of paper and paperboard and as a retention and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.1 percent by weight of the finished dry paper and paperboard fibers.
Polypropylene glycol (minimum molecular weight 1,000)	
Potassium persulfate	
Propylene glycol alginate	
Protein hydrolysate from animal hides or soybean protein condensed with oleic and/or stearic acid.	
Rapeseed oil, sulfated ammonium, potassium, or sodium salt	
Ricebran oil, sulfated ammonium, potassium, or sodium salt	
Rosin and rosin derivatives	As provided in § 178.3870 of this chapter.
Sodium carboxymethyl guar gum having a minimum viscosity of 2,700 centipoises at 25° C after 24 hours as determined by RV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 20 r.p.m. and using a test sample prepared by dissolving 8 grams of sodium carboxymethyl guar gum in 392 milliliters of 0.2-percent-by-weight aqueous sodium *o*-phenylphenate solution.	For use only as a dry-strength and formation-aid agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1% by weight of finished dry paper or paperboard fibers.
Sodium dioctyl sulfosuccinate	
Sodium formaldehyde sulfoxylate	For use only as polymerization catalyst.
Sodium hypochlorite	
Sodium *N*-methyl-*N*-oleyltaurate	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Sodium nitrite	For use only: 1. At levels not to exceed 0.2% by weight of lubricants or release agents applied at levels not to exceed 1 lb. per ton of finished paper or paperboard. 2. As an anticorrosion agent at levels not to exceed 0.2% by weight of wax emulsions used as internal sizing in the manufacture of paper and paperboard prior to the sheet-forming operation.
Sodium persulfate	
Sodium polyacrylate	For use only: 1. As a thickening agent for natural rubber latex coatings, provided it is used at a level not to exceed 2 percent by weight of coating solids. 2. As a pigment dispersant in coatings at a level not to exceed 0.25 percent by weight of pigment.
Sodium zinc potassium polyphosphate (CAS Reg. No. 65997-17-3)	For use only as a pigment dispersant in coatings at a level not to exceed 1 percent by weight of pigment.
Sperm oil, sulfated, ammonium, potassium, or sodium salt	
Stannous oleate	
Stearyl-2-lactylic acid and its calcium salt	
Styrene-butadiene copolymers produced by copolymerizing styrene-butadiene with one or more of the monomers: acrylamide, acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, methacrylic acid, and *N*-methylolacrylamide (CAS Reg. No. 53504-31-7). The finished copolymers shall contain not more than 10 weight percent of total polymer units derived from acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and methacrylic acid, and shall contain not more than 3 weight percent of total polymer units derived from *N*-methylolacrylamide, and shall contain not more than 2 weight percent of polymer units derived from acrylamide.	

List of Substances	Limitations
Styrene-maleic anhydride copolymor, amidated, ammonium sodium salt; having, in a 25 percent by weight aqueous solution at pH 8.8, a minimum viscosity of 600 centipoises at 25° C as determined by Brookfield model LVT viscometer using a No. 3 spindle at 60 r.p.m. (or equivalent method).	For use only as a surface size at a level not to exceed 1 percent by weight of paper or paperboard substrate.
Styrene-maleic anhydride copolymer, sodium salt (minimum molecular weight 30,000).	For use only: 1. As a coating thickening agent at a level not to exceed 1% by weight of coating solids. 2. As surface size at a level not to exceed 1% by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymer, potassium salt (minimum molecular weight 30,000).	For use only as a coating thickening agent at a level not to exceed 1% by weight of coating solids.
Synthetic wax polymer prepared by the catalytic polymerization of alpha olefins such that the polymer has a maximum iodine number of 18 and a minimum number average molecular weight of 2,400.	For use only as a component of petroleum wax and/or synthetic petroleum wax complying with § 178.3710 or § 178.3720 of this chapter at levels not to exceed 5 percent by weight of the wax: 1. Under conditions of use F and G described in Table 2 of paragraph (c) of this section for all foods. 2. Under conditions of use E described in Table 2 of paragraph (c) of this section for food Types I, II, IV-B, VI, VII-B and VIII as described in Table 1 of paragraph (c) of this section.
Tallow	
Tallow alcohol	
Tallow alcohol, hydrogenated	
Tallow fatty acid, hydrogenated	
Tallow hydrogenated	
Tallow sulfated, ammonium, potassium, or sodium salt	
Tetraethylenepentamine	For use only as a modifier for amino resins.
1,4,4a,9a-Tetrahydro-9, 10-anthracenedione (CAS Reg. No. 56136-14-2).	For use only as a catalyst in the alkaline pulping of lignocellulosic materials at levels not to exceed 0.1 percent by weight of the raw lignocellulosic materials.
N,N,N′, N′-Tetramethylethylenediamine polymer with bis-(2-chloroethyl) ether, first reacted with not more than 5 percent by weight 1-chloro-2,3-epoxypropane and then reacted with not more than 5 percent by weight poly (acrylic acid) such that a 50 percent by weight aqueous solution of the product has a nitrogen content of 4.7-4.9 percent and viscosity of 350-700 centipoises at 25° C as determined by LV series Brookfield viscometer using a No. 2 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a flocculent, drainage aid or retention aid employed prior to the sheet forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.2 percent by weight of the finished dry paper and paperboard fibers.
Tetrasodium *N*- (1,2-dicarboxyethyl) - *N* - octadecylsulfosuccinamate.	For use only as an emulsifier in aqueous dispersions of rosin sizes complying with § 178.3870(a)(4) of this chapter and limited to use prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.02 pct by weight of finished paper and paperboard.
Triethanolamine	For use only to adjust pH during the manufacture of amino resins permitted for use as components of paper and paperboard.
Triethylene glycol adipic acid monoester produced by reacting equimolar quantities of triethylene glycol and adipic acid.	For use only as a curl-control agent at a level not to exceed 2% by weight of coated or uncoated paper and paperboard.
Triethylenetetramine	For use only as a modifier for amino resins.
1,3,5-Triethylhexahydro-1,3,5-triazine (CAS Registry No. 7779-27-3).	For use only as an antimicrobial agent for coating, binder, pigment, filler, sizing, and similar formulations added prior to the heat drying step in the manufacture of paper and paperboard and limited to use at a level between 0.05 and 0.15 percent by weight of the formulation.
Undecafluorocyclohexanemethanol ester mixture of dihydrogen phosphate, compound with 2,2′-iminodiethanol (1:1), hydrogen phosphate, compound with 2,2′-iminodiethanol (1:1), and P,P′-dihydrogen pyrophosphate, compound with 2,2′-iminodiethanol (1:2), where the ester mixture has a fluorine content of 48.3 pct to 53.1 pct as determined on a solids basis.	For use only as an oil repellent at a level not to exceed 0.087 lb (0.046 lb of fluorine) per 1,000 ft^2 of treated paper or paperboard, as determined by analysis for total fluorine in the treated paper or paperboard without correction for any fluorine which might be present in the untreated paper or paperboard, when such paper or paperboard is used in contact with food only of the types identified in paragraph (c) of this section, Table 1, under Types IVA, V, VIIA, VIII, and IX, and under the conditions of use B through G described in Table 2 of paragraph (c) of this section.
Viscose rayon fibers	
Wax, petroleum	Complying with § 178.3710 of this chapter.

List of Substances	Limitations
Xanthan gum, conforming to the identity and specifications prescribed in § 172.695 of this chapter, except that the residual isopropyl alcohol shall not exceed 6,000 parts per million.	For use only at a maximum level of 0.125 percent by weight of finished paper as a suspension aid or stabilizer for aqueous pigment slurries employed in the manufacture of paper and paperboard.
Xylene sulfonic acid-formaldehyde condensate, sodium salt	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Zinc formaldehyde sulfoxylate	For use only as polymerization catalyst.
Zinc octoate	
Zirconium oxide	For use only as a component of waterproof coatings where the zirconium oxide is present at a level not to exceed 1 percent by weight of the dry paper or paperboard fiber and where the zirconium oxide is produced by hydrolysis of zirconium acetate.

(b) Substances identified in paragraph (b) (1) and (2) of this section may be used as components of the food-contact surface of paper and paperboard, provided that the food-contact surface of the paper or paperboard complies with the extractives limitations prescribed in paragraph (c) of this section.

(1) Substances identified in § 175.300(b)(3) of this chapter with the exception of those identified in paragraphs (b)(3) (v), (xv), (xx), (xxxi), and (xxxii) of that section and paragraph (a) of this section.

(2) Substances identified in this paragraph (b)(2) follow:

List of substances	Limitations
Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butyl alcohol.	
Acrylamide copolymerized with ethylene and vinyl chloride in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide, and in such a manner that the acrylamide portion may or may not be subsequently partially hydrolyzed.	For use only as coatings or components of coatings.
Acrylic and modified acrylic polymers	Complying with § 177.1010 of this chapter.
Acrylic copolymers produced by copolymerizing 2 or more of the acrylate monomers butyl acrylate, ethyl acrylate, ethyl methacrylate, methyl acrylate, methyl methacrylate, and *n*-propyl methacrylate, or produced by copolymerizing one or more of such acrylate monomers together with one or more of the monomers acrylic acid, acrylonitrile, butadiene, 2-ethyl-hexyl acrylate, fumaric acid, glycidyl methacrylate, *n*-hexyl-methacrylate, itaconic acid, methacrylic acid, styrene, vinyl acetate, vinyl chloride, and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from one or more of the monomers butyl acrylate, ethyl acrylate, ethyl methacrylate, methyl acrylate, methyl methacrylate, and *n*-propyl methacrylate; and shall contain not more than 5 weight percent of total polymer units derived from acrylic acid, fumaric acid, glycidyl methacrylate, *n*-hexyl methacrylate, itaconic acid, and methacrylic acid. The provision limiting the finished acrylic copolymers to not more than 5 [illegible] units derived from acrylic acid, fumaric acid, glycidyl methacrylate, *n*-hexyl methacrylate, itaconic acid, and methacrylic acid is not applicable to finished acrylic copolymers used as coating adjuvants at a level not exceeding 2 weight percent of total coating solids.	
n-Alkylsulfonate (alkyl group is in the range C_{10}-C_{18} with not less than 50 percent C_{14}-C_{16}).	For use only: 1. As an emulsifier for vinylidene chloride copolymer coatings and limited to use at a level not to exceed 2 percent by weight of the coating solids.

List of substances	Limitations
	2. As a emulsifier for vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contacts food only of types identified in paragraph (c) of this section, Table 1, under Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX and under conditions of use E, F and G described in Table 2 of paragraph (c) of this section.
2-Bromo-4'-hydroxyacetophenone	For use only as a preservative for coating formulations, binders, pigment slurries, and sizing solutions at a level not to exceed 0.006 percent by weight of the coating, solution, slurry or emulsion.
Butylbenzyl phthalate	Complying with § 178.3740 of this chapter.
Butyl oleate, sulfated, ammonium, potassium, or sodium salt.	
Butyraldehyde	
Captan (*N*-trichloromethylmercapto-4-cyclohexene-1, 2-dicarboximide).	For use only as a mold- and mildew-proofing agent in coatings intended for use in contact with food only of the types identified in paragraph (c) of this section, Table 1, under Type I, II, VI-B, and VIII.
Castor Oil, polyoxyethylated (42 moles ethylene oxide)	For use only as an emulsifier in nitrocellulose coatings for paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, Table 1, under Types IV A, V, VII A, VIII, and IX; and limited to use at a level not to exceed 8 percent by weight of the coating solids.
Cationic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyl-trimethylammonium chloride).	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (Chemical Abstracts Service Registry No. 4080-31-3).	For use only as a preservative at a level of 0.3 weight percent in latexes used as pigment binders in paper and paperboard intended for use in contact with nonacidic, nonalcoholic food and under the conditions of use described in paragraph (c) of this section, Table 2, conditions of use E, F, and G.
5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture at a ratio of 3 parts to 1 part, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2). The mixture may contain magnesium nitrate (CAS Reg. No. 10377-6-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent for polymer latex emulsions in coatings at a level not to exceed 50 parts per million (based on isothiazolone active ingredients) in the coating formulation.
Copper 8-quinolinolate	For use only as preservative for coating formulations.
Cyclized rubber produced when natural pale crepe rubber dissolved in phenol is catalytically cyclized so that the finished cyclized rubber has a melting point of 145° C to 155° C as determined by ASTM method E28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and contains no more than 4000 ppm of residual-free phenol as determined by a gas liquid chromatographic procedure titled "Determination of Free Phenol in Cyclized Rubber Resin," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	For use only in coatings for paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, Table 1, under Types VIII and IX.
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7)	For use only as a preservative at levels not more than 0.05 weight percent and not less than 0.01 weight percent in latexes used as pigment binders in coatings, in pigment slurries used in coatings, and/or in coatings themselves. The total level of the preservative in the finished coating shall not exceed 0.04 weight percent of the finished coating solids.
Dibutyl phthalate	
Dibutyl sebacate	
Di(C₇, C₉-alkyl) adipate	Complying with § 178.3740 of this chapter.
Dicyclohexyl phthalate	

List of substances	Limitations
Diethylene glycol dibenzoate (CAS Reg. No. 120-55-8)	For use only as a plasticizer for polyvinyl acetate coatings at a level not to exceed 5 percent by weight of the coating solids under conditions described in paragraph (c) of this section, table 2, conditions of use E, F, and G.
Diethylene glycol ester of the adduct of terpene and maleic anhydride.	
Dihydroxy dichlorodiphenyl methane	For use only as preservative for coating formulations.
Dimethylpolysiloxane, 100 centistokes viscosity	
Dimethylpolysiloxane-beta-phenylethyl methyl polysiloxane copolymer (2:1), 200 to 400 centistokes viscosity.	
N,N-Diphenyl-*p*-phenylenediamine	For use only as polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
Dipropylene glycol dibenzoate (CAS Reg. No. 27138-31-4)	1. For use only as a plasticizer for polyvinyl acetate coatings at a level not to exceed 5 percent by weight of the coating solids under conditions described in paragraph (c) of this section, table 2, condition of use E. 2. For use only as a plasticizer for polyvinly acetate coatings at a level not to exceed 10 percent by weight of the coating solids under conditions described in paragraph (c) of this section, table 2, conditions of use F and G.
Disodium *N*-octadecylsulfosuccinamate	For use only as an emulsifier in resin latex coatings and limited to use at a level not to exceed 0.05% by weight of the coating solids.
EDTA (ethylenediamintetraacetic acid) and its sodium and/or calcium salts.	
Ethanedial, polymer with tetrahydro-4-hydroxy-5-methyl-2(1*H*)pyrimidinone, propoxylated.	For use only as an insolubilizer for starch-based coatings and limited to use at a level not to exceed 0.2 percent by weight of the coating solids.
Ethylene acrylic acid copolymers produced by the copolymerization of ethylene and acrylic acid and/or their partial ammonium salts. The finished copolymer shall contain no more than 25 weight percent of polymer units derived from acrylic acid and no more than 0.35 weight percent of residual monomeric acrylic acid, and have a melt index not to exceed 350 as determined by ASTM method D1238-82, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	
Formaldehyde	For use only as preservative for coating formulations.
Glyoxal	For use only as an insolubilizing agent in starch- and protein-based coatings that contact nonalcoholic foods, and limited to use at a level not to exceed 6 percent by weight of the starch or protein fraction of the coating solids.
Glyceryl monobutyl ricinoleate	
Hydroxymethyl derivates (mixture of mono and poly) of [N-(1, 1-dimethyl-3-oxobutyl) acrylamide] produced by reacting 1 mole of the [N-(1-dimethyl-3-oxobutyl) acrylamide] with 3 moles of formaldehyde such that the finished product has a maximum nitrogen content of 6.2 percent and a maximum hydroxyl content of 5 percent by weight on a dry basis.	For use only as a comonomer in polyvinyl acetate latex coatings and limited to use at a level not to exceed 1 percent by weight of dry polymer solids.
Isobutyl oleate, sulfated, ammonium, potassium, or sodium salt.	
Maleic anhydride adduct of butadiene-styrene copolymer	
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Oleyl alcohol	
Oxazolidinylethylmethacrylate (CAS Registry No. 46235-15-1) copolymer with ethylacrylate and methyl methacrylate, and containing not more than 6 percent by weight of oxazolidinylethylmethacrylate; maximum nitrogen content shall be 0.5 percent and number average molecular weight of that portion of the copolymer soluble in tetrahydrofuran shall be not less than 50,000.	For use only as a binder for pigment coatings at a binder level not to exceed 4.0 percent by weight of dry paper or paperboard.
Pentaerythritol tetrastearate	

List of substances	Limitations
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, meeting the following specifications: Softening point 97° C minimum, as determined by ASTM method E28–67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring and Ball Apparatus;" aniline point 120° C minimum, as determined by ASTM method D611–82, "Standard Test Methods for Aniline Point and Mixed Aniline Point of Petroleum Products and Hydrocarbon Solvents," which are incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408). Specific gravity, 0.96–0.99 (20° C/20° C). Such petroleum hydrocarbon resins are produced by the catalytic polymerization of dienes and olefins from low-boiling distillates of cracked petroleum stocks that contain no material boiling over 200° C and that meet the ultraviolet absorbance limits prescribed in § 172.880(b) of this chapter when subjected to the analytical procedure described in § 172.886(b) of this chapter, modified as follows: Treat the product as in the first paragraph under "Procedure" in § 172.250(b)(3) of this chapter. Then proceed with § 172.886(b) of this chapter, starting with the paragraph commencing with "Promptly complete transfer of the sample * * *".	For use only as modifiers in waxpolymer blend coatings for corrugated paperboard intended for use in bulk packaging or raw fruits, raw vegetables, iced meat, iced fish, and iced poultry; and limited to use at a level not to exceed 30 weight-percent of the coating solids.
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70° C–92° C., and a color of K or paler.	
Polyester resin produced by reacting the acid groups in montan wax with ethylene glycol.	
Polyethylene, oxidized	Complying with § 177.1620 of this chapter.
Polyethylene reacted with maleic anhydride such that the modified polyethylene has a saponification number not in excess of 6 after Soxhlet extraction for 24 hours with anhydrous ethyl alcohol.	
Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt.	Not to exceed 300 p.p.m. in finished coated paper or paperboard.
Polyoxypropylene-polyoxyethylene block polymers (minimum molecular weight 6,800).	
Polyvinyl acetate	
Polyvinyl alcohol (minimum viscosity of 4% aqueous solution at 20° C. of 4 centipoises).	
Polyvinyl butyral	
Polyvinyl formal	
Polyvinylidenc chloride	
Polyvinyl pyrrolidone	
Polyvinyl stearate	
Propylene glycol mono- and diesters of fats and fatty acids	
Sodium decylbenzenesulfonate	
Sodium dihexyl sulfosuccinate	
Sodium *n*-dodecylpolyethoxy (50 moles) sulfate-sodium isododecylphenoxypolyethoxy (40 moles) sulfate mixtures.	For use only as an emulsifier in coatings that contact food only of the types identified in paragraph (c) of this section, Table 1, under Types IV–A, V, VII, VIII, and IX, and limited to use at levels not to exceed 0.75 percent by weight of the coating solids.
Sodium 2-ethylhexyl sulfate	
Sodium oleoyl isopropanolamide sulfosuccinate	
Sodium pentachlorophenate	For use only as preservative for coating formulations.
Sodium *o*-phenylphenate	Do.
Sodium vinyl sulfonate polymerized	
Styrene copolymers produced by copolymerizing styrene with maleic anhydride and its methyl and butyl (sec- or iso-) esters. Such copolymers may contain β-nitrostyrene as a polymerization chain terminator.	For use only as a coating or component of coatings and limited to use at a level not to exceed 1% by weight of paper or paperboard substrate.

List of substances	Limitations
Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (M_n) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent.	For use only in contact with foods of Types IV-A, V, and VII in table 1 of paragraph (c) of this section, under use conditions E through G in table 2 of paragraph (c), and with foods of Types VIII and IX without use temperature restriction.
Styrene-acrylic copolymers (CAS Reg. No. 25950-40-7) produced by polymerizing 77 to 83 parts by weight of styrene with 13 to 17 parts of methyl methacrylate, 3 to 4 parts of butyl methacrylate, 0.5 to 2.5 parts of methacrylic acid, and 0.1 to 0.3 part of butyl acrylate such that the finished copolymers have a minimum number average molecular weight greater than 100,000 and a level of residual styrene monomer in the polymer not to exceed 0.1 percent by weight.	For use only as a component of coatings and limited to use at a level not to exceed 20 percent by weight of the coating solids.
Styrene-butadiene copolymers produced by copolymerizing styrene-butadiene with one or more of the monomer: acrylamide, acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and methacrylic acid. The finished copolymers shall contain not more than 10 weight percent of total polymer units derived from acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid and methacrylic acid, and shall contain not more than 2 weight percent of polymer units derived from acrylamide.	
Styrene-butadiene copolymers with 2-hydroxyethyl acrylate and acrylic acid containing not more than 15 weight percent acrylic acid and no more than 20 weight percent of a combination of 2-hydroxyethyl acrylate and acrylic acid.	
Styrene-butadiene-vinylidene chloride copolymers containing not more than 40 weight percent of vinylidene chloride in the finished copolymers. The finished copolymers may contain not more than 10 weight percent of total polymer units derived from acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and/or methacrylic acid.	For use only as coatings or components of coatings.
Styrene-dimethylstyrene-α-methylstyrene copolymers produced by polymerizing equimolar ratios of the three comonomers such that the finished copolymers have a minimum average molecular weight of 635 as determined by ASTM method D2503-82, "Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	For use only in coatings for paper and paperboard intended for use in contact with nonfatty food and limited to use at a level not to exceed 50% by weight of the coating solids.
Styrene-isobutylene copolymers (weight average molecular weight not less than 6,300).	For use only in coatings for paper and paperboard intended for use in contact under conditions of use D-G described in Table 2 of paragraph (c) of this section, with food of Types I, II, IV-B, VI-B, VII-B, and VIII described in Table 1 of paragraph (c) of this section; and limited to use at a level not to exceed 40 percent by weight of the coating solids.
Styrene-maleic anhydride copolymers	For use only as a coating or component of coatings and limited for use at a level not to exceed 2 percent by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymers containing no more than 5 weight percent of polymer units derived from methacrylic acid.	
Styrene-vinylidene chloride copolymers containing not more than 40 weight percent of vinylidene chloride in the finished copolymers. The finished copolymers may contain not more than 5 weight percent of total polymer units derived from acrylic acid, fumaric acid, itaconic acid, and/or methacrylic acid.	For use only as coatings or components of coatings.
2-Sulfoethyl methacrylate, sodium salt [Chemical Abstracts Service No. 1804-87-1].	For use only in copolymer coatings under conditions of use E, F, and G described in paragraph (c) of this section, Table 2, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

List of substances	Limitations
α-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly (oxyethylene) hydrogen sulfate, sodium salt mixture with α-[*p*-(1,1,3,3-tetramethylbutyl)-phenyl]-*omega*-hydroxypoly (oxyethylene) with both substances having a poly(oxyethylene) content averaging 3 moles	For use only as a surface-active agent at levels not to exceed 3 percent by weight of vinyl acetate polymer with ethylene and *N*-(hydroxymethyl) acrylamide intended for use in coatings for paper and paperboard intended for use in contact with foods: 1. Of the types identified in paragraph (c) of this section, Table 1, under Types I, II, III, IV, VI-B, and VII, and under the conditions of use described in paragraph (c) of this section, Table 2, conditions of use E, F, and G. 2. Of the types identified in paragraph (c) of this section, Table 1, under Types V, VIII and IX and under the conditions of use described in paragraph (c) of this section, Table 2, conditions of use C, D, E, F, and G.
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecylsulfo-succinamate	For use only as an emulsifier in resin latex coatings, and limited to use at a level not to exceed 0.05% by weight of the coating solids.
Toluenesulfonamide-formaldehyde resins	
Vinyl acetate copolymers produced by copolymerizing vinyl acetate with one or more of the monomers acrylamide, acrylic acid, acrylonitrile, bicyclo-[2.2.1]*hept*-2-ene-6-methylacrylate, butyl acrylate, crotonic acid, decyl acrylate, diallyl fumarate, diallyl maleate, diallyl phthalate, dibutyl fumarate, dibutyl itaconate, dibutylmaleate, di(2-ethylhexyl) maleate, divinyl benzene, ethyl acrylate, 2-ethyl-hexyl acrylate, fumaric acid, itaconic acid, maleic acid, methacrylic acid, methyl acrylate, methyl methacrylate, mono(2-ethylhexyl) maleate, monoethyl maleate, styrene, vinyl butyrate, vinyl crotonate, vinyl hexoate, vinylidene chloride, vinyl pelargonate, vinyl propionate, vinyl pyrrolidone, vinyl stearate, and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, crotonic acid, decyl acrylate, dibutyl itaconate, di(2-ethylhexyl) maleate, fumaric acid, itaconic acid, maleic acid, methacrylic acid, mono(2-ethylhexyl) maleate, monoethyl maleate, vinyl butyrate, vinyl hexoate, vinyl pelargonate, vinyl propionate, vinyl stearate, and vinyl sulfonic acid.	
Vinyl acetate polymer with ethylene and *N*-(hydroxymethyl) acrylamide containing not more than 6 weight percent of total polymer units derived from *N*-(hydroxymethyl) acrylamide.	For use only in coatings for paper and paperboard intended for use in contact with foods: 1. Of the types identified in paragraph (c) of this section, Table 1, under Types I, II, III, IV, VI-B, and VII and under the conditions of use described in paragraph (c) of this section, Table 2, conditions of use E, F, and G. 2. Of the types identified in paragraph (c) of this section, Table 1, under Types V, VIII, and IX and under the conditions of use described in paragraph (c) of this section, Table 2, conditions of use C, D, E, F, and G.
Vinyl chloride copolymers produced by copolymerizing vinyl chloride with one or more of the monomers acrylonitrile; fumaric acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic anhydride; 5-norbornene-2, 3-dicarboxylic acid, mono-*n*-butyl ester; vinyl acetate-and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl chloride; shall contain no more than 5 weight percent of total polymer units derived from fumaric and/or maleic acid and/or their methyl, ethyl, propyl, butyl, amyl, heptyl, or octyl monoesters or from maleic anhydride or from mono-*n*-butyl ester of 5-norbornene-2, 3-dicarboxylic acid (however, in any case the finished copolymers shall contain no more than 4 weight percent of total polymer units derived from mono-*n*-butyl ester of 5-norbornene-2,3-dicarboxylic acid).	
Vinyl chloride-vinyl acetate hydroxyl-modified copolymers.	
Vinyl chloride-vinyl acetate hydroxyl-modified copolymers reacted with trimellitic anhydride.	

List of substances	Limitations
Vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylamide acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, ethyl methacrylate, fumaric acid, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, octadecyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinylidene chloride, and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.	

(c) The food-contact surface of the paper and paperboard in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of this paragraph, shall yield net chloroform-soluble extractives (corrected for wax, petrolatum, mineral oil and zinc extractives as zinc oleate) not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in paragraph (d) of this section.

TABLE 1—TYPES OF RAW AND PROCESSED FOODS

I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
IV. Dairy products and modifications:
  A. Water-in-oil emulsions, high- or low-fat.
  B. Oil-in-water emulsions, high- or low-fat.
V. Low-moisture fats and oil.
VI. Beverages:
  A. Containing up to 8 percent of alcohol.
  B. Nonalcoholic.
  C. Containing more than 8 percent alcohol.
VII. Bakery products other than those included under Types VIII or IX of this table:
  A. Moist bakery products with surface containing free fat or oil.
  B. Moist bakery products with surface containing no free fat or oil.
VIII. Dry solids with the surface containing no free fat or oil (no end test required).
IX. Dry solids with the surface containing free fat or oil.

TABLE 2—TEST PROCEDURES WITH TIME TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM THE FOOD-CONTACT SURFACE OF UNCOATED OR COATED PAPER AND PAPERBOARD, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Condition of use	Types of food (see Table 1)	Food-simulating solvents			
		Water [2]	Heptane [1] [2]	8 percent alcohol [2]	50 percent alcohol [2]
A. High temperature heat-sterilized (e.g., over 212° F)	I, IV-B, VII-B	250° F, 2 hr			
	III, IV-A, VII-A	do	150° F, 2 hr		
B. Boiling water sterilized	II, VII-B	212° F, 30 min			
	III, VII-A	do	120° F, 30 min		
C. Hot filled or pasteurized above 150° F	II, IV-B, VII-B	Fill boiling, cool to 100° F			
	III, IV-A, VII-A	do	120° F, 15 min		

TABLE 2—TEST PROCEDURES WITH TIME TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM THE FOOD-CONTACT SURFACE OF UNCOATED OR COATED PAPER AND PAPERBOARD, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES—Continued

Condition of use	Types of food (see Table 1)	Food-simulating solvents			
		Water[2]	Heptane[1,2]	8 percent alcohol[2]	50 percent alcohol[2]
	V, IX		do		
D. Hot filled or pasteurized below 150° F	II, IV-B, VI-B, VII-B	150° F, 2 hr			
	III, IV-A, VII-A	do	100° F, 30 min		
	V, IX		do		
	VI-A			150° F, 2 hr	
	VI-C				150° F, 2 hr
E. Room temperature filled and stored (no thermal treatment in the container)	I, II, IV-B, VI-B, VII-B	120° F, 24 hr			
	III, IV-A, VII-A	do	70° F, 30 min		
	V, IX		do		
	VI-A			120° F, 24 hr	
	VI-C				120° F, 24 hr
F. Refrigerated storage (no thermal treatment in the container)	III, IV-A, VII-A	70° F, 48 hr	70° F, 30 min		
	I, II, IV-B, VI-B, VII-B	do			
	VI-A			70° F, 48 hr	
	VI-C				70° F, 48 hr
G. Frozen storage (no thermal treatment in the container)	I, II, IV-B, VII-B	70° F, 24 hr			
	III, VII-A	do	70° F, 30 min		
H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:					
1. Aqueous or oil-in-water emulsion of high- or low-fat	I, II, IV-B, VII-B	212° F, 30 min			
2. Aqueous, high- or low-free oil or fat	III, IV-A, VII-A, IX	do	120° F, 30 min		

[1] Heptane extractability results must be divided by a factor of five in arriving at the extractability for a food product having water-in-oil emulsion or free oil or fat. Heptane food-simulating solvent is not required in the case of wax-polymer blend coatings for corrugated paperboard containers intended for use in bulk packaging of iced meat, iced fish, and iced poultry.

[2] Time and temparature.

(d) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food product (Table 1, paragraph (c) of this section) that is being packed commercially in the paper or paperboard and the normal conditions of thermal treatment used in packaging the type of food involved. Using Table 2, paragraph (c) of this section, select the food-simulating solvent or solvents and the time-temperature exaggerations of the paper or paperboard use conditions. Having selected the appropriate food-simulating solvent or solvents and the time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) *Reagents*—(i) *Water.* All water used in extraction procedures should be freshly demineralized (deionized) distilled water.

(ii) *n-Heptane.* Reagent grade, freshly redistilled before use, using only material boiling at 208° F.

(iii) *Alcohol.* 8 or 50 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized (deionized) distilled water.

(iv) *Chloroform.* Reagent grade, freshly redistilled before use, or a grade having an established consistently low blank.

(3) *Selection of test method.* Paper or paperboard ready for use in packaging shall be tested by use of the extraction cell described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980),

sections 21.010-21.015, under "Exposing Flexible Barrier Materials for Extraction," which is incorporated by reference (copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408); also described in ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), except that formed paper and paperboard products may be tested in the container by adapting the in-container methods described in § 175.300(e) of this chapter. Formed paper and paperboard products such as containers and lids, that cannot be tested satisfactorily by any of the above methods may be tested in specially designed extraction equipment, usually consisting of clamping devices that fit the closure or container so that the food-contact surface can be tested, or, if flat samples can be cut from the formed paper or paperboard products without destroying the integrity of the food-contact surface, they may be tested by adapting the following "sandwich" method:

(i) *Apparatus.* (*a*) Thermostated (±1.0° F) water bath, variable between 70° F and 120° F water bath cover capable of holding at least one 800-milliliter beaker partially submersed in bath.

(*b*) Analytical balance sensitive to 0.1 milligram with an approximate capacity of 100 grams.

(*c*) Tongs.

(*d*) Hood and hot-plate facilities.

(*e*) Forced draft oven.

For each extraction, the following additional apparatus is necessary:

(*f*) One No. 2 paper clip.

(*g*) One 800-milliliter beaker with watch-glass cover.

(*h*) One 250-milliliter beaker.

(*i*) Five 2½-inch-square aluminum screens (standard aluminum window screening is acceptable).

(*j*) One wire capable of supporting sample stack.

(ii) *Procedure.* (*a*) For each extraction, accurately cut eight 2½-inch-square samples from the formed paper or paperboard product to be tested.

(*b*) Carefully stack the eight 2½-inch-square samples and the five 2½-inch-square aluminum screens in sandwich form such that the food-contact side of each sample is always next to an aluminum screen, as follows: Screen, sample, sample, screen, sample, sample, screen, etc. Clip the sandwich together carefully with a No. 2 paper clip, leaving just enough space at the top to slip a wire through.

(*c*) Place an 800-milliliter beaker containing 100-milliliters of the appropriate food-simulating solvent into the constant temperature bath, cover with a watch glass and condition at the desired temperature.

(*d*) After conditioning, carefully lower the sample sandwich with tongs into the beaker.

(*e*) At the end of the extraction period, using the tongs, carefully lift out the sample sandwich and hang it over the beaker with the wire.

(*f*) After draining, pour the food-simulating solvent solution into a tared 250-milliliter beaker. Rinse the 800-milliliter beaker three times, using a total of not more than 50 milliliters of the required solvent.

(*g*) Determine total nonvolatile extractives in accordance with paragraph (d)(5) of this section.

(4) *Selection of samples.* Quadruplicate samples should be tested, using for each replicate sample the number of cups, containers, or preformed or converted products nearest to an area of 100 square inches.

(5) *Determination of amount of extractives*—(i) *Total residues.* At the end of the exposure period, remove the test container or test cell from the oven and combine the solvent for each replicate in a clean Pyrex (or equivalent) flask or beaker being sure to rinse the test container or cell with a small quantity of clean solvent. Evaporate the food-simulating solvents to about 100 milliliters in the flask or

beaker, and transfer to a clean, tared evaporating dish (platinum or Pyrex), washing the flask three times with small portions of solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking, low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of approximately 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram, (*e*). Calculate the extractives in milligrams per square inch of the container or sheeted paper or paperboard surface.

(*a*) *Water and 8- and 50-percent alcohol.* Milligrams extractives per square inch = (*e*)/(*s*).

(*b*) *Heptane.* Milligrams extractives per square inch = (*e*)/(*s*)(*F*)

Where:

e = Milligrams extractives per sample tested.

s = Surface area tested, in square inches.

F = Five, the ratio of the amount of extractives removed by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil under exaggerated conditions of thermal sterilization and use.

e′ = Chloroform-soluble extractives residue.

ee′ = Corrected chloroform-soluble extractives residue.

e′ or *ee′* is substituted for *e* in the above equations when necessary.

If when calculated by the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section, the extractives in milligrams per square inch exceeds the limitations prescribed in paragraph (c) of this section, proceed to paragraph (d)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residues).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (*e*), in the evaporating dish obtained in paragraph (d)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper (or equivalent) in a Pyrex (or equivalent) funnel, collecting the filtrate in a clean, tared evaporating dish (platinum or Pyrex). Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at approximately 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (*e′*). This *e′* is substituted for *e* in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section. If the chloroform-soluble extractives in milligrams per square inch still exceeds the limitation prescribed in paragraph (c) of this section, proceed to paragraph (d)(5)(iii) of this section (method for determining corrected chloroform-soluble extractives residue).

(iii) *Corrected chloroform-soluble extractives residue*—(*a*) *Correction for zinc extractives.* Ash the residue in the evaporating dish by heating gently over a Meker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the evaporating dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (*e′*) to obtain the zinc-corrected chloroform-soluble extractives residue (*ee′*). This *ee′* is substituted for *e* in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section.

(*b*) *Correction for wax, petrolatum, and mineral oil*—(*1*) *Apparatus.* Standard 10 millimeter inside diameter x 60 centimeter chromatographic column (or standard 50-milliliter buret with an inside diameter of 10-11 millimeters) with a stopcock of glass, perfluorocarbon resin, or equivalent material. The column (or buret) may be optionally equipped with an integral coarse, fritted glass disc and the top of the column (or buret) may be optionally fitted with a 100-millimeter solvent reservoir.

(*2*) *Preparation of column.* Place a snug pledget of fine glass wool in the bottom of the column (or buret) if the column (or buret) is not equipped with integral coarse, fritted glass disc. Overlay the glass wool pledget (or fritted glass disc) with a 15-20 millimeter deep layer of fine sand. Measure in a graduated cylinder 15 milliliters of chromatographic grade aluminum oxide (80-200 mesh) that has been tightly settled by tapping the cylinder. Transfer the aluminum oxide to the chromatographic tube, tapping the tube during and after the transfer so as to tightly settle the aluminum oxide. Overlay the layer of aluminum oxide with a 1.0-1.5 centimeter deep layer of anhydrous sodium sulfate and on top of this place an 8-10 millimeter thick plug of fine glass wool. Next carefully add about 25 milliliters of heptane to the column with stopcock open, and allow the heptane to pass through the column until the top level of the liquid just passes into the top glass wool plug in the column, and close stopcock.

(*3*) *Chromatographing of sample extract*—(*i*) *For chloroform residues weighing 0.5 gram or less.* To the dried and weighed chloroform-soluble extract residue in the evaporating dish, obtained in paragraph (d)(5)(ii) of this section, add 20 milliliters of heptane and stir. If necessary, heat carefully to dissolve the residue. Additional heptane not to exceed a total volume of 50 milliliters may be used if necessary to complete dissolving. Cool to room temperature. (If solution becomes cloudy, use the procedure in paragraph (d)(5)(iii)(*b*)(*3*)(*ii*) of this section to obtain an aliquot of heptane solution calculated to contain 0.1-0.5 gram of chloroform-soluble extract residue.) Transfer the clear liquid solution to the column (or buret). Rinse the dish with 10 millimeters of additional heptane and add to column. Allow the liquid to pass through the column into a clean, tared evaporating dish (platinum or Pyrex) at a dropwise rate of about 2 milliliters per minute until the liquid surface reaches the top glass wool plug; then close the stopcock temporarily. Rinse the Pyrex flask which contained the filtrate with an additional 10-15 milliliters of heptane and add to the column. Wash (elute) the column with more heptane collecting about 100 milliliters of total eluate including that already collected in the evaporating dish. Evaporate the combined eluate in the evaporating dish to dryness on a steam bath. Dry the residue for 15 minutes in an oven maintained at a temperature of approximately 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram. Subtract the weight of the residue from the weight of chloroform-soluble extractives residue (*e*′) to obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (*ee*′). This *ee*′ is substituted for *e* in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section.

(*ii*) *For chloroform residues weighing more than 0.5 gram.* Redissolve the dried and weighed chloroform-soluble extract residue as described in paragraph (d)(5)(iii)(*b*)(*3*)(*i*) of this section using proportionately larger quantities of heptane. Transfer the heptane solution to an appropriate-sized volumetric flask (i.e., a 250-milliliter flask for about 2.5 grams of residue) and adjust to volume with additional heptane. Pipette out an aliquot (about 50 milliliters) calculated to contain 0.1-0.5 gram of the chloroform-soluble extract residue and analyze chromatographically as described in paragraph (d)(5)(iii)(*b*)(*3*)(*i*) of this section. In this case the weight of the dried residue from the heptane eluate must be multiplied by the dilution factor to obtain the weight of wax, petrolatum, and mineral oil residue to be subtracted from the weight of chloroform-soluble extractives residue (*e*′) to obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (*ee*′). This *ee*′ is substituted for *e* in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section. (Note: In the case of chloroform-soluble extracts which contain high melting waxes (melting point greater than 170° F), it may be necessary to dilute the heptane solution further so that a 50-milliliter aliquot will contain only 0.1-0.2 gram of the chloroform-soluble extract residue.)

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter, except where the copolymers are restricted to use in contact with food only of the type identified in paragraph (c), Table 1 under Category VIII.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting § 176.170, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 176.180 Components of paper and paperboard in contact with dry food.

The substances listed in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food of the type identified in § 176.170(c), Table 1, under Type VIII, subject to the provisions of this section.

(a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.

(b) The substances permitted to be used include the following:

(1) Substances that by § 176.170 and other applicable regulations in Parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

(2) Substances identified in the following list:

List of substances	Limitations
(2-Alkenyl) succinic anhydrides in which the alkenyl groups are derived from olefins which contain not less than 78 percent C_{30} and higher groups (CAS Reg. No. 70983-55-0)	
4-[2-[2-(2-Alkoxy(C_{12}–C_{14}) ethoxy) ethoxy]ethyl]disodium sulfosuccinate	For use as a polymerization emulsifier and latex emulsion stabilizer at levels not to exceed 5 percent by weight of total emulsion solids.
Aluminum and calcium salts of FD & C dyes on a substrate of alumina	Colorant.
Ammonium nitrate	
Amylose	
Barium metaborate	For use as preservative in coatings and sizings.
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5)	For use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.12 mg/in² (0.0031 mg/cm²) of finished paper and paperboard.
N,N-Bis(hydroxyethyl)lauramide	
Bis(trichloromethyl) sulfone C.A. Registry No. 3064-70-8	For use only as a preservative in coatings.
Borax	For use as preservative in coatings.
Boric acid	Do.
sec-Butyl alcohol	
Butyl benzyl phthalate	
Candelilla wax	
Carbon tetrachloride	
Castor oil, polyoxyethylated (42 moles ethylene oxide)	
Cationic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyl-trimethylammonium chloride)	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
Cationic soy protein (soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethyl-ammonium chloride)	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
Chloral hydrate	Polymerization reaction-control agent.
N-Cyclohexyl-*p*-toluene sulfonamide	
2,5-Di-*tert*-butyl hydroquinone	
Diethanolamine	
Diethylene glycol dibenzoate (CAS Reg. No. 120-55-8)	For use only as a plasticizer in polymeric substances.
Diethylene glycol monobutyl ether	
Diethylene glycol monoethyl ether	
Diethylenetriamine	
N,N-Diisopropanolamide of tallow fatty acids	
N-[(dimethylamino)methyl]acrylamide polymer with acrylamide and styrene	

List of substances	Limitations
N,N-Dioleoylethylenediamine, *N,N*-dilinoeoyl-ethylenediamine, and N-oleoyl-N-linoleoyl-ethylenediamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°-228° F, as determined by ASTM method D127-60, and an acid value of 10 maximum. ASTM Method D127-60 "Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax" (Revised 1960) is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	
Diphenylamine	
Dipropylene glycol dibenzoate (CAS Reg. No. 27138-31-4)	For use only as plasticizer in polymeric substances.
Disodium *N*-octadecylsulfosuccinamate	
tert-Dodecyl thioether of polyethylene glycol	
Erucamide (erucylamide)	
Ethanedial, polymer with tetrahydro-4-hydroxy-5-methyl-2(1*H*)pyrimidinone, propoxylated.	
Ethylene oxide	Fumigant in sizing.
Ethylene oxide adduct of mono-(2-ethylhexyl) *o*-phosphate	
Fatty acid (C_{12}–C_{18}) diethanolamide	
Fish oil fatty acids, hydrogenated, potassium salt	
Formaldehyde	
Glyceryl monocaprate	
Glyoxal	
Glyoxal-urea-formaldehyde condensate (CAS Reg. No. 27013-01-0) formed by reaction in the molar ratio of approximately 47:33:15, respectively. The reaction product has a number average molecular weight of 278±14 as determined by a suitable method.	For use as an insolubilizer for starch in coatings.
Glyoxal-urea polymer (CAS Reg. No. 53037-34-6)	For use as an insolubilizer for starch.
Hexamethylenetetramine	Polymerization crosslinking agent for protein, including casein. As neutralizing agent with myristochromic chloride complex and stearato-chromic chloride complex.
Hexylene glycol (2-methyl-2,4-pentanediol)	
Hydroabietyl alcohol	
5-Hydroxymethoxymethyl-1-aza-3,7-dioxabicyclo[3.3.0] octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-hydroxypoly-[methyleneoxy]methyl-1-aza-3,7-dioxabicyclo[3.3.0] octane mixture.	For use only as an antibacterial preservative.
Isopropanolamine hydrochloride	
Isopropyl *m*- and *p*-cresol (thymol derived)	
Itaconic acid	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt.	
Melamine-formaldehyde modified with: Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl). Diethylenetriamine. Imino-bis-butylamine. Imino-bis-ethyleneimine. Imino-bis-propylamine. Polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane. Sulfanilic acid. Tetraethylenepentamine. Triethylenetetramine.	Basic polymer.
Methyl alcohol	
Methyl esters of mono-, di-, and tripropylene glycol	
Methyl napthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Methylated poly(*N*-1,2-dihydroxyethylene-1,3-imidazolidin-2-one).	For use only only as an in solubilizer for starch
Modified polyacrylamide resulting from an epichlorohydrin addition to a condensate of formaldehyde-dicyandiamide-diethylene triamine and which product is then reacted with polyacrylamide and urea to produce a resin having a nitrogen content of 5.6 to 6.3 percent and having a minimum viscosity in 56 percent-by-weight aqueous solution of 200 centipoises at 25° C, as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 60 r.p.m. (or equivalent method).	For use only as a dry strength and pigment retention aid agent employed prior to the sheetforming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of dry fibers.
Monoglyceride citrate	

List of substances	Limitations
Myristo chromic chloride complex	
Napthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Nickel	
β-Nitrostyrene	Basic polymer.
α-*cis*-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages not less than 20 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles.	
Oleic acid reacted with *N*-alkyl-(C_{14}–C_{18}) trimethylenediamine	
Oxidized soy isolate having 50 to 70 percent of its cystine residues oxidized to cysteic acid.	For use as a binder achesive component of coatings.
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with the identity prescribed in § 176.170(b)(2).	For use as modifiers at levels up to 30 weight-percent of the solids content of wax-polymer blend coatings.
Petroleum hydrocarbon resins (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).	
Petroleum hydrocarbons, light and odorless	
Petroleum sulfonates	
o-Phthalic acid modified hydrolyzed soy protein isolate	
Pine oil	
Poly(2-aminoethyl acrylate nitrate-*co*-2-hydroxypropyl acrylate) complying with the identity described in § 176.170(a).	
Polyamide-epichloro hydrin modified resins resulting from the reaction of the initial caprolactam-itaconic acid product with diethylenetriamine and then condensing this prepolymer with epichlorohydrin to form a cationic resin having a nitrogen content of 11–15 percent and chlorine level of 20–23 percent on a dry basis.	
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.	
Poly [2-(diethylamino) ethyl methacrylate] phosphate	
Polyethylene glycol (200) dilaurate	
Polymers: Homopolymers and copolymers of the following monomers:	Basic polymer.
Acrylamide.	
Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters.	
Acrylonitrile.	
Butadiene.	
Crotonic acid.	
Cyclol acrylate.	
Decyl acrylate.	
Diallyl fumarate.	
Diallyl maleate.	
Diallyl phthalate.	
Dibutyl fumarate.	
Dibutyl itaconate.	
Dibutyl maleate.	
Di(2-ethylhexyl) maleate.	
Dioctyl fumarate.	
Dioctyl maleate.	
Divinylbenzene.	
Ethylene.	
2-Ethylhexyl acrylate.	
Fumaric acid.	
Glycidyl methacrylate.	
2-Hydroxyethyl acrylate.	
N-(Hydroxymethyl) acrylamide.	
Isobutyl acrylate.	
Isobutylene.	
Isoprene.	
Itaconic acid.	
Maleic anhydride and its methyl or butyl esters.	
Methacrylic acid and its methyl, ethyl, butyl, or propyl esters.	
Methylstyrene.	
Mono(2-ethylhexyl) maleate.	

List of substances	Limitations
Monoethyl maleate.	
5-Norbornene-2,3-dicarboxylic acid, mono-*n*-butyl ester.	
Styrene.	
Vinyl acetate.	
Vinyl butyrate.	
Vinyl chloride.	
Vinyl crotonate.	
Vinyl hexoate.	
Vinylidene chloride.	
Vinyl pelargonate.	
Vinyl propionate.	
Vinyl pyrrolidone.	
Vinyl stearate.	
Vinyl sulfonic acid.	
Polyoxyethylene (minimum 12 moles) ester of tall oil (30%–40% rosin acids).	
Polyoxypropylene-polyoxyethylene glycol (minimum molecular weight 1,900).	
Polyvinyl alcohol	
Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20–0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of $K_2Ti_4O_9$ and $K_2Ti_6O_{13}$.	
Sodium diisobutylphenoxy diethoxyethyl sulfonate	
Sodium diisobutylphenoxy monoethoxy ethylsulfonate	
Sodium *n*-dodecylpolyethoxy (50 moles) sulfate	
Sodium isododecylphenoxypolyethoxy (40 moles) sulfate	
Sodium *N*-methyl-*N*-oleyl taurate	
Sodium methyl siliconate	
Sodium nitrite	
Sodium polyacrylate	
Sodium bis-tridecylsulfosuccinate	
Sodium xylene sulfonate	
Stearato chromic chloride complex	
Styrene-allyl alcohol copolymers	
Styrene-methacrylic acid copolymer, potassium salt	
Tetraethylenepentamine	Polymerization cross-linking agent.
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-*omega* hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles.	
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl or *p*-nonylphenyl]-*omega*-hydroxypoly (oxyethylene) where nonyl group is a propylene trimer isomer.	
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecyl sulfosuccinamate.	
Toluene	
Triethanolamine	
Triethylenetetramine	Polymerization cross-linking agent.
Triethylenetetramine monoacetate, partially stearoylated	
Urea-formaldehyde chemically modified with:	
Alcohol (methyl, ethyl, butyl, isobutyl, propyl, or isopropyl).	
Aminomethylsulfonic acid.	
Diaminobutane.	
Diaminopropane.	
Diethylenetriamine.	
N,N′-Dioleoylethylenediamine.	
Diphenylamine.	
N,N′-Distearoylethylenediamine.	
Ethylenediamine.	
Guanidine.	
Imino-bis-butylamine.	
Imino-bis-ethylamine.	
Imino-bis-propylamine.	
N-Oleoyl-*N*′-stearoylethylenediamine.	
Polyamines made by reacting ethylenediamine or triethylenediamine with dichloroethane or dichloropropane.	
Tetraethylenepentamine.	
Triethylenetetramine.	
Xylene	

List of substances	Limitations
Xylene sulfonic acid-formaldehyde condensate, sodium salt	
Zinc stearate	

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting § 176.180, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 176.200 Defoaming agents used in coatings.

The defoaming agents described in this section may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.

(b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or technical effect in the defoaming agents or any limitation further provided.

(c) Any substance employed in the production of defoaming agents and which is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the formulation of defoaming agents include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in defoaming agents and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

List of substances	Limitations
n-Butyl alcohol	
tert-Butyl alcohol	
Butyl stearate	
Castor oil, sulfated, ammonium, potassium, or sodium salt	
Cetyl alcohol	
Cyclohexane	
Cyclohexanol	
Diethylene glycol monolaurate	
Diethylene glycol monostearate	
Dimers and trimers of unsaturated C_{18} fatty acids derived from:	For use only at levels not to exceed 0.1% by weight of total coating solids.
Animal and vegetable fats and oils.	
Tall oil.	
Dimethylpolysiloxane	
Dipropylene glycol	
Ethyl alcohol	
Fats and oils derived from animal, marine, or vegetable sources.	
Fatty acids derived from animal, marine, or vegetable fats and oils, and salts of such acids, single or mixed, as follows:	
Aluminum.	
Ammonium.	
Calcium.	
Magnesium.	
Potassium.	
Sodium.	
Zinc.	
Formaldehyde	For use as preservative of defoamer only.
Glyceryl mono-12-hydroxystearate	
Glyceryl monostearate	
Hexane	
Hexylene glycol (2-methyl-2,4-pentanediol)	
Isobutyl alcohol	
Isopropyl alcohol	

List of substances	Limitations
Kerosene	
Lecithin hydroxylated	
Methyl alcohol	
Methylcellulose	
Methyl esters of fatty acids derived from animal, marine, or vegetable fats and oils.	
Methyl oleate	
Methyl palmitate	
Mineral oil	
Mustardseed oil, sulfated, ammonium, potassium, or sodium salt.	
Myristyl alcohol	
Naphtha	
β-Naphthol	For use as preservative of defoamer only.
Nonylphenol	
Odorless light petroleum hydrocarbons	As defined in § 178.3650 of this chapter.
Oleic acid, sulfated, ammonium, potassium, or sodium salt	
Parachlorometacresol	For use as preservative of defoamer only.
Peanut oil, sulfated, ammonium, potassium, or sodium salt	
Petrolatum	
Pine oil	
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane.
Polyethylene	
Polyethylene, oxidized	
Polyethylene glycol (200) dilaurate	
Polyethylene glycol (400) dioleate	
Polyethylene glycol (600) dioleate	
Polyethylene glycol (400) esters of coconut oil fatty acids	
Polyethylene glycol (400) monooleate	
Polyethylene glycol (600) monooleate	
Polyethylene glycol (600) monoricinoleate	
Polyethylene glycol (400) monostearate	
Polyoxybutylene-polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 3,700).	
Polyoxyethylated (min. 3 mols) cetyl alcohol	
Polyoxyethylated (min. 5 mols) oleyl alcohol	
Polyoxyethylated (min. 1.5 mols) tridecyl alcohol	
Polyoxyethylene (min. 15 mols) ester of rosin	
Polyoxyethylene (min. 8 mols) monooleate	
Polyoxyethylene (40) stearate	
Polyoxypropylated (min. 20 mols) butyl alcohol	
Polyoxypropylene glycol (min. mol. wt. 200)	
Polyoxypropylene (min. 20 mols) oleate butyl ether	
Polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 1,900)	
Polyoxypropylene (min. 40 mols) stearate butyl ether	
Potassium pentachlorophenate	For use as preservative of defoamer only.
Potassium trichlorophenate	Do.
Propylene glycol monoester of soybean oil fatty acids	
Propylene glycol monoester of tallow fatty acids	
Ricebran oil, sulfated, ammonium, potassium, or sodium salt	
Rosins and rosin derivatives	As provided in § 178.3870 of this chapter.
Silica	
Sodium 2-mercaptobenzothiazole	For use as preservative of defoamer only.
Sodium pentachlorophenate	Do.
Sodium trichlorophenate	Do.
Sperm oil, sulfated, ammonium, potassium, or sodium salt	
Stearyl alcohol	
Tall oil fatty acids	
Tallow fatty acids, hydrogenated or sulfated	
Tallow, sulfated, ammonium, potassium, or sodium salt	
Triethanolamine	
Triisopropanolamine	
Waxes, petroleum	

(e) The defoaming agents are used as follows:

(1) The quantity of defoaming agent or agents used shall not exceed the amount reasonably required to accomplish the intended effect, which is to prevent or control the formation of foam.

(2) The defoaming agents are used in the preparation and application of coatings for paper and paperboard.

§ 176.210 Defoaming agents used in the manufacture of paper and paperboard.

Defoaming agents may be safely used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The defoaming agents are prepared from one or more of the substances named in paragraph (d) of this section, subject to any prescribed limitations.

(b) The defoaming agents are used to prevent or control the formation of foam during the manufacture of paper and paperboard prior to and during the sheet-forming process.

(c) The quantity of defoaming agent or agents added during the manufacturing process shall not exceed the amount necessary to accomplish the intended technical effect.

(d) Substances permitted to be used in the formulation of defoaming agents include substances subject to prior sanctions or approval for such use and employed subject to the conditions of such sanctions or approvals, substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, and substances listed in this paragraph, subject to the limitations, if any, prescribed.

(1) Fatty triglycerides, and the fatty acids, alcohols, and dimers derived therefrom:

Beef tallow.
Castor oil.
Coconut oil.
Corn oil.
Cottonseed oil.
Fish oil.
Lard oil.
Linseed oil.
Mustardseed oil.
Palm oil.
Peanut oil.
Rapeseed oil.
Ricebran oil.
Soybean oil.
Sperm oil.
Tall oil.

(2) Fatty triglycerides, and marine oils, and the fatty acids and alcohols derived therefrom (paragraph (d)(1) of this section) reacted with one or more of the following, with or without dehydration, to form chemicals of the category indicated in parentheses:

Aluminum hydroxide (soaps).
Ammonia (amides).
Butanol (esters).
Butoxy-polyoxypropylene, molecular weight 1,000-2,500 (esters).
Butylene glycol (esters).
Calcium hydroxide (soaps).
Diethanolamine (amides).
Diethylene glycol (esters).
Ethylene glycol (esters).
Ethylene oxide (esters and ethers).
Glycerin (mono- and diglycerides).
Hydrogen (hydrogenated compounds).
Hydrogen (amines).
Isobutanol (esters).
Isopropanol (esters).
Magnesium hydroxide (soaps).
Methanol (esters).
Morpholine (soaps).
Oxygen (air-blown oils).
Pentaerythritol (esters).
Polyoxyethylene, molecular weights 200, 300, 400, 600, 700, 1,000, 1,540, 1,580, 1,760, 4,600 (esters).
Polyoxypropylene, molecular weight 200-2,000 (esters).
Potassium hydroxide (soaps).
Propanol (esters).
Propylene glycol (esters).
Propylene oxide (esters).
Sodium hydroxide (soaps).
Sorbitol (esters).
Sulfuric acid (sulfated and sulfonated compounds).
Triethanolamine (amides and soaps).
Triisopropanolamine (amides and soaps).
Trimethylolethane (esters).
Zinc hydroxide (soaps).

(3) Miscellaneous:

Alcohols and ketone alcohols mixture (still-bottom product from C_{12}-C_{18} alcohol manufacturing process).
Amyl alcohol.
Butoxy polyethylene polypropylene glycol molecular weight 900-4,200.
Butoxy-polyoxypropylene molecular weight 1,000-2,500.
Butylated hydroxyanisole.
Butylated hydroxytoluene.
Calcium lignin sulfonate.
Capryl alcohol.
p-Chlorometacresol.
Cyclohexanol.
Diacetyltartaric acid ester of tallow monoglyceride.
Diethanolamine.
Diethylene triamine.
Di-(2-ethylhexyl) phthalate.

2,6-Dimethyl heptanol-4 (nonyl alcohol).
Dimethylpolysiloxane.
Di-*tert*-butyl hydroquinone.
Dodecylbenzene sulfonic acids.
Ethanol.
2-Ethylhexanol.
Ethylenediamine tetraacetic acid tetrasodium salt.
Formaldehyde.
Heavy oxo-fraction (a still-bottom product of iso-octyl alcohol manufacture, of approximate composition: Octyl alcohol 5 percent nonyl alcohol 10 percent, decyl and higher alcohols 35 percent, esters 45 percent, and soaps 5 percent).
2-Heptadecenyl-4-methyl-4-hydroxymethyl-2-oxazoline.
Hexylene glycol (2-methyl-2-4-pentanediol).
12-Hydroxystearic acid.
Isobutanol.
Isopropanol.
Isopropylamine salt of dodecylbenzene sulfonic acid.
Kersosine.
Lanolin.
Methanol.
Methyl 12-hydroxystearate.
Methyl taurine-oleic acid condensate, molecular weight 486.
a,a'-[Methylenebis[4-(1,1,3,3-tetramethylbutyl)-*o*-phenylene]]*bis*[*omega*-hydroxypoly (oxyethylene)] having 6-7.5 moles of ethylene oxide per hydroxyl group.
Mineral oil.
Mono-, di-, and triisopropanolamine.
Mono and diisopropanolamine stearate.
Monobutyl ether of ethylene glycol.
Monoethanolamine.
Morpholine.
Myristyl alcohol.
Naphtha.
β-Naphthol.
Nonylphenol.
Odorless light petroleum hydrocarbons.
Oleyl alcohol.
Petrolatum.
o-Phenylphenol.
Pine oil.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.
Polyethylene.
Polyethylene, oxidized (air-blown).
Polymer derived from *N*-vinyl pyrrolidone and copolymers derived from the mixed alkyl (C_{12}-C_{15}, C_{16}, C_{18}, C_{20}, and C_{22}) methacrylate esters, butyl methacrylate (CAS Reg. No. 97-88-1), isobutyl methacrylate (CAS Reg. No. 97-86-9) and methyl methacrylate (CAS Reg. No. 80-62-6); the combined polymer contains no more than 5 weight percent of polymer units derived from *N*-vinyl pyrrolidone and is present at a level not to exceed 7 parts per million by weight of the finished dry paper and paperboard fibers.
Polyoxyethylene (4 mols) decyl phosphate.
Polyoxyethylene (4 mols) di(2-ethyl hexanoate).
Polyoxyethylene (15 mols) ester of rosin.
Polyoxyethylene (3-15 mols) tridecyl alcohol.
Polyoxypropylene, molecular weight 200-2,000.
Polyoxypropylene-polyoxethylene condensate, minimum molecular weight 950.
Polyoxypropylene-ethylene oxide condensate of ethylene diamine, molecular weight 1,700-3,800.
Polyvinyl pyrrolidone, molecular weight 40,000.
Potassium distearyl phosphate.
Potassium pentachlorophenate.
Potassium trichlorophenate.
Rosins and rosin derivatives identified in § 175.105(c)(5) of this chapter.
Silica.
Siloxanes and silicones, dimethyl, methylhydrogen, reaction products with polyethylene-polypropylene glycol monoallyl ether (CAS Reg. No. 71965-38-3).
Sodium alkyl (C_9-C_{15}) benzene-sulfonate.
Sodium dioctyl sulfosuccinate.
Sodium distearyl phosphate.
Sodium lauryl sulfate.
Sodium lignin sulfonate.
Sodium 2-mercaptobenzothiazole.
Sodium naphthalenesulfonic acid (3 mols) condensed with formaldehyde (2 mols).
Sodium orthophenylphenate.
Sodium pentachlorophenate.
Sodium petroleum sulfonate, molecular weight 440-450.
Sodium trichlorophenate.
Stearyl alcohol.
a-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl-, *p*-nonylphenyl-, or *p*-dodecylphenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-alkylphenol (alkyl group is 1,1,3,3-tetramethylbutyl, a propylene trimer isomer, or a propylene tetramer isomer) with an average of 1.5-15 moles of ethylene oxide.
Tetrahydrofurfuryl alcohol.
Tributoxyethyl phosphate.
Tributyl phosphate.
Tridecyl alcohol.
Triethanolamine.
Triethylene glycol di(2-ethyl hexanoate).
Tri-(2-ethylhexyl) phosphate.
Tristearyl phosphate.
Wax, petroleum, Type I and Type II.
Wax, petroleum (oxidized).
Wax (montan).

[42 FR 14554, Mar. 15, 1977, as amended at 47 FR 17986, Apr. 27, 1982; 47 FR 46495, Oct. 19, 1982; 47 FR 56845, Dec. 21, 1982]

§ 176.230 3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.

3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione may safely be used as a preservative in the manufacture and coating of paper and paperboard intended for use in contact with food in accordance with the following prescribed conditions:

(a) It is used as follows:

(1) In the manufacture of paper and paperboard as a preservative for substances added to the pulp suspension prior to the sheet-forming operation provided that the preservative is volatilized by heat in the drying and finishing of the paper and paperboard.

(2) As a preservative for coatings for paper and paperboard, *Provided*, That the preservative is volatilized by heat in the drying and finishing of the coated paper or paperboard.

(b) The quantity used shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any physical or technical effect in the food itself.

(c) The use of a preservative in any substance or article subject to any regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications and limitations prescribed by such regulation for the substance or article.

§ 176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.

Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane may be safely used as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food in an amount not to exceed that necessary to accomplish the intended physical or technical effect and not to exceed 6 pounds per ton of finished paper or paperboard.

§ 176.260 Pulp from reclaimed fiber.

(a) Pulp from reclaimed fiber may be safely used as a component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of paragraph (b) of this section.

(b) Pulp from reclaimed fiber is prepared from the paper and paperboard products described in paragraphs (b)(1) and (2) of this section, by repulping with water to recover the fiber with the least possible amount of nonfibrous substances.

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act.

(2) Salvage from used paper and paperboard excluding that which (i) bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the act or (ii) has been used for shipping or handling any such substance.

§ 176.300 Slimicides.

(a) Slimicides may be safely used in the manufacture of paper and paperboard that contact food, in accordance with the following prescribed conditions:

(1) Slimicides are used as antimicrobial agents to control slime in the manufacture of paper and paperboard.

(2) Subject to any prescribed limitations, slimicides are prepared from one or more of the slime-control substances named in paragraph (c) of this section to which may be added optional adjuvant substances as provided for under paragraph (d) of this section.

(3) Slimicides are added to the process water used in the production of paper or paperboard, and the quantity added shall not exceed the amount necessary to accomplish the intended technical effect.

(b) To insure safe usage, the label or labeling of slimicides shall bear adequate directions for use.

(c) Slime-control substances permitted for use in the preparation of slimicides include substances subject to prior sanction or approval for such use and the following:

List of substances	Limitations
Acrolein	
Alkenyl (C_{16}–C_{18}) dimethylethyl-ammonium bromide	
n-Alkyl (C_{12}–C_{18}) dimethyl benzyl ammonium chloride	
1,2-Benzisothiazolin-3-one	At a level of 0.06 pound per ton of dry weight fiber.
Bis(1,4-bromoacetoxy)-2-butene	
5,5-Bis(bromoacetoxymethyl) *m*-dioxane	
2,6-Bis(dimethylaminomethyl) cyclohexanone	
1,2-Bis(monobromoacetoxy) ethane [CA Reg. No. 3785-34-0]	At a maximum level of 0.10 pound per ton of dry weight fiber.
Bis(trichloromethyl)sulfone	
4-Bromoacetoxymethyl-*m*-dioxolane	
2-Bromo-4′-hydroxyacetophenone	
β-Bromo-*β*-nitrostyrene	At a maximum level of 1 pound per ton of dry weight fiber.
Chloroethylenebisthiocyanate	
5-Chloro-2 - methyl - 4 - isothiazolin-3-one calcium chloride and 2-methyl-4-isothiazolin-3-one calcium chloride mixture at a ratio of 3 parts to 1 part.	At a level of 2.5 pounds per ton of dry weight fiber.
Chlorinated levulinic acids	
Chloromethyl butanethiolsulfonate	
Cupric nitrate	
n-Dialkyl (C_{12}–C_{18}) benzylmethylammonium chloride	
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35691-65-7)	At a maximum level of 0.005% of dry weight fiber.
2,2-Dibromo-3-nitrilopropionamide	At a maximum level of 0.1 lb/ton of dry weight fiber.
2,3-Dibromopropionaldehyde	
3,5-Dimethyl 1,3,5,2*H*-tetrahydrothiadiazine-2-thione	
Dipotassium and disodium ethylenebis(dithiocarba-mate)	
Disodium cyanodithioimidocarbonate	
n-Dodecylguanidine hydrochloride	At a maximum level of 0.20 pound per ton of dry weight fiber.
2-(*p*-hydroxyphenyl) glyoxylohydroximoyl chloride (CAS Registry No. 34911-46-1)	At a level of 0.02 pound per ton of dry weight fiber.
2-Hydroxypropyl methanethiol sulfonate	
2-Mercaptobenzothiazole	
Methylenebisbutanethiolsulfonate	
Methylenebisthiocyanate	
2-Nitrobutyl bromoacetate [CA Reg. No. 32815-96-6]	At a maximum level of 0.15 pound per ton of dry weight fiber.
N-[*α*-(Nitroethyl)benzyl] ethylenediamine	
Potassium 2-mercaptobenzothiazole	
Potassium *N*-hydroxymethyl-*N*-methyldithiocarba-mate	
Potassium *N*-methyldithiocarbamate	
Potassium pentachlorophenate	
Potassium trichlorophenate	
Silver fluoride	Limit of addition to process water not to exceed 0.024 pound, calculated as silver fluoride, per ton of paper produced.
Silver nitrate	
Sodium dimethyldithiocarbamate	
Sodium 2-mercaptobenzothiazole	
Sodium pentachlorophenate	
Sodium trichlorophenate	
1,3,6,8-Tetraazatricyclo[6.2.1.$1^{3,6}$] dodecane	
3,3,4,4-Tetrachlorotetrahydrothiophene-1,1-dioxide	
2-(Thiocyanomethylthio) benzothiazole	
Vinylene bisthiocyanate	

(d) Adjuvant substances permitted to be used in the preparation of slimicides include substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, substances permitted to be used in paper and paperboard by other regulations in this chapter, and the following:

Acetone.
Butylene oxide.
Dibutyl phthalate.
Didecyl phthalate.
N,N-Dimethylformamide.
Dodecyl phthalate.
Ethanolamine.
Ethylene glycol.
Ethylenediamine.
N-methyl-2-pyrrolidone (CAS Reg. No. 872-50-4).
α,α′-[Methylenebis[4-(1,1,3,3-tetramethylbutyl)-*o*-phenylene]] *bis*[*omega*-hydroxypoly (oxyethylene)] having 6-7.5 moles of ethylene oxide per hydroxyl group.
Monomethyl ethers of mono-, di-, and tripropylene glycol.
Nonylphenol reaction product with 9 to 12 molecules of ethylene oxide.
Octylphenol reaction product with 25 molecules of propylene oxide and 40 molecules of ethylene oxide.

[42 FR 14554, Mar. 15, 1977, as amended at 42 FR 41854, Aug. 19, 1977; 44 FR 75627, Dec. 21, 1979; 46 FR 36129, July 14, 1981; 49 FR 5748, Feb. 15, 1984; 51 FR 19059, May 27, 1986; 51 FR 43734, Dec. 4, 1986]

§ 176.320 Sodium nitrate-urea complex.

Sodium nitrate-urea complex may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Sodium nitrate-urea complex is a clathrate of approximately two parts urea and one part sodium nitrate.

(b) Sodium nitrate-urea complex conforming to the limitations prescribed in paragraph (b)(1) of this section is used as provided in paragraph (b)(2) of this section.

(1) *Limitations.* (i) It is used as a plasticizer in glassine and greaseproof paper.

(ii) The amount used does not exceed that required to accomplish its intended technical effect or exceed 15 percent by weight of the finished paper.

(2) *Conditions of use.* The glassine and greaseproof papers are used for packaging dry food or as the food-contact surface for dry food.

§ 176.350 Tamarind seed kernel powder.

Tamarind seed kernel powder may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Tamarind seed kernel powder is the ground kernel of tamarind seed (*Tamarindus indica* L.) after removal of the seed coat.

(b) It is used in the manufacture of paper and paperboard.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

Subpart A—[Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec.
177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.
177.1020 Acrylonitrile/butadiene/styrene co-polymer.
177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.
177.1040 Acrylonitrile/styrene copolymer.
177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.
177.1200 Cellophane.
177.1210 Closures with sealing gaskets for food containers.
177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.
177.1310 Ethylene-acrylic acid copolymers.
177.1315 Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers.
177.1320 Ethylene-ethyl acrylate copolymers.
177.1330 Ionomeric resins.
177.1340 Ethylene-methyl acrylate copolymer resins.
177.1350 Ethylene-vinyl acetate copolymers.
177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.
177.1380 Fluorocarbon resins.
177.1390 High-temperature laminates.
177.1400 Hydroxyethyl cellulose film, water-insoluble.
177.1420 Isobutylene polymers.
177.1430 Isobutylene-butene copolymers.
177.1440 4,4′-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.
177.1460 Melamine-formaldehyde resins in molded articles.
177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.
177.1500 Nylon resins.
177.1520 Olefin polymers.
177.1550 Perfluorocarbon resins.
177.1560 Polyarylsulfone resins.
177.1570 Poly-1-butene resins and butene/ethylene copolymers.
177.1580 Polycarbonate resins.
177.1590 Polyester elastomers.
177.1595 Polyetherimide resin.
177.1600 Polyethylene resins, carboxyl modified.
177.1610 Polyethylene, chlorinated.
177.1615 Polyethylene, fluorinated.

Sec.
177.1620 Polyethylene, oxidized.
177.1630 Polyethylene phthalate polymers.
177.1635 Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene).
177.1640 Polystyrene and rubber-modified polystyrene.
177.1650 Polysulfide polymer-polyepoxy resins.
177.1655 Polysulfone resins.
177.1660 Poly (tetramethylene terephthalate).
177.1670 Polyvinyl alcohol film.
177.1680 Polyurethane resins.
177.1810 Styrene block polymers.
177.1820 Styrene-maleic anhydride copolymers.
177.1830 Styrene-methyl methacrylate copolymers.
177.1850 Textryls.
177.1900 Urea-formaldehyde resins in molded articles.
177.1950 Vinyl chloride-ethylene copolymers.
177.1960 Vinyl chloride-hexene-1 copolymers.
177.1970 Vinyl chloride-lauryl vinyl ether copolymers.
177.1980 Vinyl chloride-propylene copolymers.
177.1990 Vinylidene chloride/methyl acrylate copolymers.
177.2000 Vinylidene chloride/methyl acrylate/methyl methacrylate polymers.

Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

177.2210 Ethylene polymer, chlorosulfonated.
177.2250 Filters, microporous polymeric.
177.2260 Filters, resin-bonded.
177.2280 4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins.
177.2355 Mineral reinforced nylon resins.
177.2400 Perfluorocarbon cured elastomers.
177.2410 Phenolic resins in molded articles.
177.2420 Polyester resins, cross-linked.
177.2430 Polyether resins, chlorinated.
177.2440 Polyethersulfone resins.
177.2450 Polyamide-imide resins.
177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins.
177.2470 Polyoxymethylene copolymer.
177.2480 Polyoxymethylene homopolymer.
177.2490 Polyphenylene sulfide resins.
177.2510 Polyvinylidene fluoride resins.
177.2550 Reverse osmosis membranes.
177.2600 Rubber articles intended for repeated use.
177.2710 Styrene-divinylbenzene resins, cross-linked.
177.2800 Textiles and textile fibers.
177.2910 Ultra-filtration membranes.

AUTHORITY: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

SOURCE: 42 FR 14572, Mar. 15, 1977, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

§ 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.

Semirigid and rigid acrylic and modified acrylic plastics may be safely used as articles intended for use in contact with food, in accordance with the following prescribed conditions. The acrylic and modified acrylic polymers or plastics described in this section also may be safely used as components of articles intended for use in contact with food.

(a) The optional substances that may be used in the formulation of the semirigid and rigid acrylic and modified acrylic plastics, or in the formulation of acrylic and modified acrylic components of articles, include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, substances permitted for use in such plastics by regulations in Parts 170 through 189 of this chapter, and substances identified in this paragraph. At least 50 weight-percent of the polymer content of the acrylic and modified acrylic materials used as finished articles or as components of articles shall consist of polymer units derived from one or more of the acrylic or methacrylic monomers listed in paragraph (a)(1) of this section.

(1) Homopolymers and copolymers of the following monomers:

n-Butyl acrylate.
n-Butyl methacrylate.
Ethyl acrylate.
2-Ethylhexyl acrylate.
Ethyl methacrylate.
Methyl acrylate.
Methyl methacrylate.

(2) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1) of this sec-

tion with one or more of the following monomers:

Acrylonitrile.
Methacrylonitrile.
α-Methylstyrene.
Styrene.
Vinyl chloride.
Vinylidene chloride.

(3) Polymers identified in paragraphs (a)(1) and (2) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the monomers listed in paragraph (a)(3)(i) and (ii) of this section. Monomers listed in paragraph (a)(3)(ii) of this section are limited to use only in plastic articles intended for repeated use in contact with food.

(i) List of minor monomers:

Acrylamide.
Acrylic acid
1,3-Butylene glycol dimethacrylate.
1,4-Butylene glycol dimethacrylate.
Diethylene glycol dimethacrylate.
Diproplylene glycol dimethacrylate.
Divinylbenzene.
Ethylene glycol dimethacrylate.
Itaconic acid.
Methacrylic acid.
N-Methylolacrylamide.
N-Methylolmethacrylamide.
4-Methyl-1,4-pentanediol dimethacrylate.
Propylene glycol dimethacrylate.
Trivinylbenzene.

(ii) List of minor monomers limited to use only in plastic articles intended for repeated use in contact with food:

Allyl methacrylate [Chemical Abstracts Service Registry No. 96-05-9]
tert-Butyl acrylate.
tert-Butylaminoethyl methacrylate.
sec-Butyl methacrylate.
tert-Butyl methacrylate.
Cyclohexyl methacrylate.
Dimethylaminoethyl methacrylate.
2-Ethylhexyl methacrylate.
Hydroxyethyl methacrylate.
Hydroxyethyl vinyl sulfide.
Hydroxypropyl methacrylate.
Isobornyl methacrylate.
Isobutyl methacrylate.
Isopropyl acrylate.
Isopropyl methacrylate.
Methacrylamide.
Methacrylamidoethylene urea.
Methacryloxyacetamidoethylethylene urea.
Methacryloxyacetic acid.
n-Propyl methacrylate.
3,5,5-Trimethylcyclohexyl methacrylate.

(4) Polymers identified in paragraphs (a)(1), (2), and (3) of this section are mixed together and/or with the following polymers, provided that no chemical reactions, other than addition reactions, occur when they are mixed:

Butadiene-acrylonitrile copolymers.
Butadiene-acrylonitrile-styrene copolymers.
Butadiene-acrylonitrile-styrene-methyl methacrylic copolymers.
Butadiene-styrene copolymers.
Butyl rubber.
Natural rubber.
Polybutadiene.
Poly (3-chloro-1,3-butadiene).
Polyester identified in § 175.300(b)(3)(vii) of this chapter.
Polyvinyl chloride.
Vinyl chloride copolymers complying with § 177.1980.
Vinyl chloride-vinyl acetate copolymers.

(5) Antioxidants and stabilizers identified in § 175.300(b)(3)(xxx) of this chapter and the following:

Di-*tert*-butyl-*p*-cresol.
2-Hydroxy-4-methoxybenzophenone.
2-Hydroxy-4-methoxy-2-carboxybenzophenone.
3-Hydroxyphenyl benzoate.
p-Methoxyphenol.
Methyl salicylate.
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3): For use only: (1) At levels not exceeding 0.2 percent by weight in semirigid and rigid acrylic and modified acrylic plastics, where the finished articles contact foods containing not more than 15 percent alcohol; and (2) at levels not exceeding 0.01 percent by weight in semirigid and rigid acrylic and modified acrylic plastics intended for repeated food-contact use where the finished article may be used for foods containing more than 15 percent alcohol.
Phenyl salicylate.

(6) Release agents: Fatty acids derived from animal and vegetable fats and oils, and fatty alcohols derived from such acids.

(7) Surface active agent: Sodium dodecylbenzenesulfonate.

(8) Miscellaneous materials:

Di(2-ethylhexyl) phthalate, for use only as a flow promoter at a level not to exceed 3 weight-percent based on the monomers.
Dimethyl phthalate.
Oxalic acid, for use only as a polymerization catalyst aid.

Tetraethylenepentamine, for use only as a catalyst activator at a level not to exceed 0.5 weight-percent based on the monomers.
Toluene.
Xylene.

(b) The semirigid and rigid acrylic and modified acrylic plastics, in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall yield extractives not to exceed the following, when tested by the methods prescribed in paragraph (c) of this section. The acrylic and modified acrylic polymers or plastics intended to be used as components of articles also shall yield extractives not to exceed the following limitations when prepared as strips as described in paragraph (c)(2) of this section:

(1) Total nonvolatile extractives not to exceed 0.3 milligram per square inch of surface tested.

(2) Potassium permanganate oxidizable distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.15.

(3) Ultraviolet-absorbing distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.30.

(4) Ultraviolet-absorbing *n*-heptane extractives not to exceed an absorbance of 0.10.

(c) *Analytical methods*—(1) *Selection of extractability conditions.* These are to be chosen as provided in § 176.170(c) of this chapter.

(2) *Preparation of samples.* Sufficient samples to allow duplicates of all applicable tests shall be cut from the articles or formed from the plastic composition under tests, as strips about 2.5 inches by about 0.85-inch wide by about 0.125-inch thick. The total exposed surface should be 5 square inches ±0.5-square inch. The samples, after preparation, shall be washed with a clean brush under hot tapwater, rinsed under running hot tapwater (140° F minimum), rinsed with distilled water, and air-dried in a dust-free area or in a desiccator.

(3) *Preparation of solvents.* The water used shall be double-distilled water, prepared in a still using a block tin condenser. The 8 and 50 percent (by volume) alcohol solvents shall be prepared from ethyl alcohol meeting the specifications of the United States Pharmacopeia XX and diluted with double-distilled water that has been prepared in a still using a tin block condenser. The *n*-heptane shall be spectrophotometric grade. Adequate precautions must be taken to keep all solvents dust-free.

(4) *Blank values on solvents.* (i) Duplicate determinations of residual solids shall be run on samples of each solvent that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. Sixty milliliters of exposed solvent is pipetted into a clean, weighed platinum dish, evaporated to 2-5 milliliters on a nonsparking, low-temperature hot plate and dried in 212° F oven for 30 minutes. The residue for each solvent shall be determined by weight and the average residue weight used as the blank value in the total solids determination set out in paragraph (c)(6) of this section. The residue for an acceptable solvent sample shall not exceed 0.5 milligram per 60 milliliters.

(ii) For acceptability in the ultraviolet absorbers test, a sample of each solvent shall be scanned in an ultraviolet spectrophotometer in 5-centimeter silica spectrophotometric absorption cells. The absorbance of the distilled water when measured versus air in the reference cell shall not exceed 0.03 at any point in the wavelength region of 245 to 310 mμ. The absorbance of the 8 percent alcohol when measured versus distilled water in the reference cell shall not exceed 0.01 at any point in the wavelength region of 245 to 310 mμ. The absorbance of the 50 percent alcohol when measured versus distilled water in the reference cell shall not exceed 0.05 at any point in the wavelength region of 245 to 310 mμ. The absorbance of the heptane when measured versus distilled water in the reference cell shall not exceed 0.15 at 245, 0.09 at 260, 0.04 at 270, and 0.02 at any point in the wavelength region of 280 to 310 mμ.

(iii) Duplicate ultraviolet blank determinations shall be run on samples of each solvent that has been exposed to the temperature-time conditions of the extraction test without the plastic sample. An aliquot of the exposed solvent shall be measured versus the unexposed solvent in the reference cell. The average difference in the absorbances at any wavelength in the region of 245 to 310 mμ shall be used as a blank correction for the ultraviolet absorbers measured at the same wavelength according to paragraph (c)(8)(ii) of this section.

(iv) The acceptability of the solvents for use in the permanganate test shall be determined by preparing duplicate permanganate test blanks according to paragraph (c)(7)(iv) of this section. For this test, the directions referring to the sample extract shall be disregarded. The blanks shall be scanned in 5-centimeter silica spectrophotometric cells in the spectrophotometer versus the appropriate solvent as reference. The absorbance in distilled water in the wavelength region of 544 to 552 mμ should be 1.16 but must not be less than 1.05 nor more than 1.25. The absorbance in the 8 and 50 percent alcohol must not be less than 0.85 nor more than 1.15.

(v) Duplicate permanganate test determinations shall be run on samples of distilled water and 8 and 50 percent alcohol solvents that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. The procedure shall be as described in paragraph (c)(7)(iv) of this section, except that the appropriate exposed solvent shall be substituted where the directions call for sample extract. The average difference in the absorbances in the region of 544 to 552 mμ shall be used as a blank correction for the determination of permanganate oxidizable extractives according to paragraph (c)(7)(iv) of this section.

(5) *Extraction procedure.* For each extraction, place a plastic sample in a clean 25 millimeters × 200 millimeters hard-glass test tube and add solvent equal to 10 milliliters of solvent per square inch of plastic surface. This amount will be between 45 milliliters and 55 milliliters. The solvent must be preequilibrated to the temperature of the extraction test. Close the test tube with a ground-glass stopper and expose to the specified temperature for the specified time. Cool the tube and contents to room temperature if necessary.

(6) *Determination of total nonvolatile extractives.* Remove the plastic strip from the solvent with a pair of clean forceps and wash the strip with 5 milliliters of the appropriate solvent, adding the washings to the contents of the test tube. Pour the contents of the test tube into a clean, weighed platinum dish. Wash the tube with 5 milliliters of the appropriate solvent and add the solvent to the platinum dish. Evaporate the solvent to 2-5 milliliters on a nonsparking, low-temperature hotplate. Complete the evaporation in a 212° F oven for 30 minutes. Cool the dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Calculate the total nonvolatile extractives as follows:

Milligrams extractives per square inch =

$$\frac{e-b}{s}$$

Extractives in parts per million =

$$\frac{eb}{s} \times 100$$

where:

e = Total increase in weight of the dish, in milligrams.

b = Blank value of the solvent in milligrams, as determined in paragraph (c)(4)(i) of this section.

s = Total surface of the plastic sample in square inches.

(7) *Determination of potassium permanganate oxidizable extractives.* (i) Pipette 25 milliliters of distilled water into a clean 125-milliliter Erlenmeyer flask that has been rinsed several times with aliquots of distilled water. This is the blank. Prepare a distilled water solution containing 1.0 part per million of *p*-methoxyphenol (melting point 54-56° C, Eastman grade or equivalent). Pipette 25 milliliters of this *p*-methoxyphenol solution into a

rinsed Erlenmeyer flask. Pipette exactly 3.0 milliliters of 154 parts per million aqueous potassium permanganate solution into the *p*-methoxyphenol and exactly 3.0 milliliters into the blank, in that order. Swirl both flasks to mix the contents and then transfer aliquots from each flask into matched 5-centimeter spectrophotometric absorption cells. The cells are placed in the spectrophotometer cell compartment with the *p*-methoxyphenol solution in the reference beam. Spectrophotometric measurement is conducted as in paragraph (c)(7)(iv) of this section. The absorbance reading in the region 544–552 mμ should be 0.24 but must be not less than 0.12 nor more than 0.36. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations in paragraph (b)(2) of this section, the absorbance measurements obtained on the distilled water extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.24}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to this paragraph (c)(7)(i) of this section}}$$

=Correction factor for water extracts.

(ii) The procedure in paragraph (c)(7)(i) of this section is repeated except that, in this instance, the solvent shall be 8 percent alcohol. The absorbance in the region 544–552 mμ should be 0.26 but must be not less than 0.13 nor more than 0.39. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b)(2) of this section, the absorbance measurements obtained on the 8 percent alcohol extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.26}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determination according to this paragraph (c)(7)(ii) of this section}}$$

=Correction factor for aqueous 8 percent alcohol extracts.

(iii) The procedure in paragraph (c)(7)(i) of this section is repeated except that, in this instance, the solvent shall be 50 percent alcohol. The absorbance in the region 544–552 mμ should be 0.25 but must be not less than 0.12 nor more than 0.38. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b)(2) of this section, the absorbance measurements obtained on the 50 percent alcohol extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.25}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to paragraph (c)(7)(ii) of this section}}$$

=Correction factor for 50 percent aqueous alcohol extracts.

(iv) *Water and 8 and 50 percent alcohol extracts.* Pipette 25 milliliters of the appropriate solvent into a clean, 125-milliliter Erlenmeyer flask that has been rinsed several times with aliquots of the same solvent. This is the blank. Into another similarly rinsed flask, pipette 25 milliliters of the sample extract that has been exposed under the conditions specified in paragraph (c)(5) of this section. Pipette exactly 3.0 milliliters of 154 parts per million aqueous potassium permanganate solution into the sample and exactly 3.0 milliliters into the blank, in that order. Before use, the potassium permanganate solution shall be checked as in paragraph (c)(7)(i) of this section. Both flasks are swirled to mix the contents, and then aliquots from each flask are transferred to matched 5-centimeter spectrophotometric absorption cells. Both cells are placed in the spectrophotometer cell compartment with the sample solution in the reference beam. The spectrophotometer is adjusted for 0 and 100 percent transmittance at 700 mμ. The spectrum is scanned on the absorbance scale from 700 mμ to 500 mμ in such a way that the region 544 mμ to 552 mμ is scanned within 5 minutes to 10 minutes of the time that permanganate was added to the solutions. The height of the absorbance peak shall be measured, corrected for the blank as determined in paragraph (c)(4)(v) of this section, and multiplied by the appropriate correction factor determined according to paragraph (c)(7) (i), (ii), and (iii) of this section. This test shall be run in duplicate and the two results averaged.

(8) *Determination of ultraviolet-absorbing extractives.* (i) A distilled water solution containing 1.0 part per million of *p*-methoxyphenol (melting point 54° C-56° C, Eastman grade or equivalent) shall be scanned in the region 360 to 220 mμ in 5-centimeter silica spectrophotometric absorption cells versus a distilled water reference. The absorbance at the wavelength of maximum absorbance (should be about 285 mμ) is about 0.11 but must be not less than 0.08 nor more than 0.14. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b) (3) and (4) of this section, the absorbance obtained on the extracts according to paragraph (c)(8)(ii) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.11}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to this paragraph (c)(8)(i) of this section}}$$

=Correction factor for ultraviolet absorbers test.

(ii) An aliquot of the extract that has been exposed under the conditions specified in paragraph (c)(5) of this section is scanned in the wavelength region 360 to 220 mμ versus the appropriate solvent reference in matched 5-centimeter silica spectrophotometric absorption cells. The height of any absorption peak shall be measured, corrected for the blank as determined in paragraph (c)(4)(iii) of this section, and multiplied by the correction factor determined according to paragraph (c)(8)(i) of this section.

(d) In accordance with current good manufacturing practice, finished semirigid and rigid acrylic and modified acrylic plastics, and articles containing these polymers, intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(f) The acrylic and modified acrylic polymers identified in and complying with this section, when used as components of the food-contact surface of an article that is the subject of a regulation in this part and in Parts 174, 175, 176, and 178 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376); secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 43 FR 54927, Nov. 24, 1978; 45 FR 67320, Oct. 10, 1980; 46 FR 46796, Sept. 22, 1981; 49 FR 10108, Mar. 19, 1984; 49 FR 13139, Apr. 3, 1984; 50 FR 31045, July 24, 1985]

§ 177.1020 Acrylonitrile/butadiene/styrene co-polymer.

Acrylonitrile/butadiene/styrene copolymer identified in this section may be safely used as an article or component of articles intended for use with all foods, except those containing alcohol, under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.

(a) *Identity.* For the purpose of this section, the acrylonitrile/butadiene/styrene copolymer consists of:

(1) Eighty-four to eighty-nine parts by weight of a matrix polymer containing 73 to 78 parts by weight of acrylonitrile and 22 to 27 parts by weight of styrene; and

(2) Eleven to sixteen parts by weight of a grafted rubber consisting of (i) 8 to 13 parts of butadiene/styrene elastomer containing 72 to 77 parts by weight of butadiene and 23 to 28 parts by weight of styrene and (ii) 3 to 8 parts by weight of a graft polymer having the same composition range as the matrix polymer.

(b) *Adjuvants.* The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part, and the following:

Substance	Limitations
2-Mercapto- ethanol	The finished copolymer shall contain not more than 100 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method titled "Analysis of Cycopac Resin for Residual β-(2-Hydroxyethylmercapto) propionitrile," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington DC 20408.

(c) *Specifications.* (1) Nitrogen content of the copolymer is in the range of 16 to 18.5 percent as determined by Micro-Kjeldahl analysis.

(2) Residual acrylonitrile monomer content of the finished copolymer articles is not more than 11 parts per million as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *Extractive limitations.* (1) Total nonvolatile extractives not to exceed 0.0005 milligram per square inch surface area when the finished food contact article is exposed to distilled water, 3 percent acetic acid, or *n*-heptane for 8 days at 120° F.

(2) The finished food-contact article shall yield not more than 0.0015 milligram per square inch of acrylonitrile monomer when exposed to distilled water and 3 percent acetic acid at 150° F for 15 days when analyzed by a polarographic method titled "Extracted Acrylonitrile by Differential Pulse Polarography," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(f) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

(Secs. 201(s), 402, 52 Stat. 1046-1047 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342))

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982]

§ 177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.

Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer identified in this section may be safely used as an article or component of articles intended for use with food identified in Table 1 of § 176.170(c) of this chapter as Type I, II, III, IVA, IVB, V, VIB, (except bottles intended to hold carbonated beverages), VIIA, VIIB, VIII and IX, under conditions of use C, D, E, F, and G described in Table 2 of § 176.170(c) of this chapter with a high temperature limitation of 190° F.

(a) *Identity.* For the purpose of this section, acrylonitrile/butadiene/styrene/methyl methacrylate copolymer consists of: (1) 73 to 79 parts by weight of a matrix polymer containing 64 to 69 parts by weight of acrylonitrile, 25 to 30 parts by weight of styrene and 4 to 6 parts by weight of methyl methacrylate; and (2) 21 to 27 parts by weight of a grafted rubber consisting of (i) 16 to 20 parts of butadiene/styrene/elastomer containing 72 to 77 parts by weight of butadiene and 23 to 28 parts by weight of styrene and (ii) 5 to 10 parts by weight of a graft polymer having the same composition range as the matrix polymer.

(b) *Adjuvants.* The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

Substances	Limitations
2-Mercaptoethanol	The finished copolymer shall contain not more than 800 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method titled "Analysis of Cycopac Resin for Residual β-(2-Hydroxyethylmercapto) propionitrile," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408

(c) *Specifications.* (1) Nitrogen content of the copolymer is in the range of 13.0 to 16.0 percent as determined by Micro-Kjeldahl analysis.

(2) Residual acrylonitrile monomer content of the finished copolymer articles is not more than 11 parts per million as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *Extractive limitations.* (1) Total nonvolatile extractives not to exceed 0.0005 milligram per square inch surface area of the food-contact article when exposed to distilled water, 3 percent acetic acid, 50 percent ethanol, and *n*-heptane for 10 days at 120° F.

(2) The finished food-contact article shall yield not more than 0.0025 milligram per square inch of acrylonitrile monomer when exposed to distilled water, 3 percent acetic acid and *n*-heptane at 190° F for 2 hours, cooled to 120° F (80 to 90 minutes) and maintained at 120° F for 10 days when analyzed by a polarographic method titled "Extracted Acrylonitrile by Differential Pulse Polarography," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(f) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

(Secs. 201(s), 402, 52 Stat. 1046-1047 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342))

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982]

§ 177.1040 Acrylonitrile/styrene copolymer.

Acrylonitrile/styrene copolymers identified in this section may be safely used as a component of packaging materials subject to the provisions of this section.

(a) *Identity.* For the purposes of this section acrylonitrile/styrene copolymers are basic copolymers meeting the specifications prescribed in paragraph (c) of this section.

(b) *Adjuvants.* (1) The copolymers identified in paragraph (c) of this section may contain adjuvant substances required in their production, with the exception that they shall not contain mercaptans or other substances which form reversible complexes with acrylonitrile monomer. Permissible adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and those authorized in paragraph (b)(2) of this section.

(2) The optional adjuvants for the acrylonitrile/styrene copolymer identified in paragraphs (c) (1) and (3) of this section are as follows:

Substances	Limitation
Condensation polymer of toluene sulfonamide and formaldehyde.	0.15 pct maximum.

(c) *Specifications.*

Acrylonitrile/styrene copolymers	Maximum residual acrylonitrile monomer content of finished article	Nitrogen content of copolymer	Maximum extractable fractions at specified temperatures and times	Conformance with certain specifications
1. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 66–72 parts by weight of acrylonitrile and 28–34 parts by weight of styrene; for use with food of Type VI-B identified in Table 1 of § 176.170(c) of this chapter under conditions of use C, D, E, F, G described in Table 2 of § 176.170(c) of this chapter.	80 ppm[1]	17.4 to 19 pct.	Total nonvolatile extractives not to exceed 0.01 mg/in^2 surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F). The extracted copolymer shall not exceed 0.001 mg/in^2 surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F)[1]	Minimum number average molecular weight is 30,000.[1]
2. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 45–65 parts by weight of acrylonitrile and 35–55 parts by weigth of styrene; for use with food of Types, I, II, III, IV, V, VI (except bottles), VII, VIII, and IX identified in Table 1 of § 176.170(c) of this chapter under conditions B (not to exceed 93 °C (200 °F)), C, D, E, F, G described in Table 2 of § 176.170(c) of this chapter.	50 ppm[1]	12.2 to 17.2 pct.	Extracted copolymer not to exceed 2.0 ppm in aqueous extract or *n*-heptane extract obtained when 100 g sample of the basic copolymer in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10 is extracted with 250 mil of deionized water or reagent grade *n*-heptane at reflux temperature for 2 h.[1]	Minimum 10 pct solution viscosity at 25 °C (77 °F) is 10cP.[1]
3. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 66–72 parts by weight of acrylonitrile and 28–34 parts by weight of styrene; for use with food of Type VI-B identified in Table 1 of § 176.170(c) of this chapter under conditions of use C, D, E, F, G described in Table 2 of § 176.170(c) of this chapter.	0.10 ppm (calculated on the basis of the weight of the acrylonitrile copolymer resin in the finished articles).[2]	17.4 to 19 pct.	Total nonvolatile extractives not to exceed 0.01 mg/in^2 surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F). The extracted copolymer shall not exceed 0.001 mg/in^2 surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 66 °C (150 °F).[1]	Maximum carbon dioxide permeability at 23 °C (73 °F) for the finished article is 0.04 barrer.[3]

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[1] Use methods for determination of residual acrylonitrile monomer content, maximum extractable fraction, number average molecular weight, and solution viscosity, titled: "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method"; "Infrared Spectrophotometric Determination of Polymer Extracted from Barex 210 Resin Pellets"; "Procedure for the Determination of Molecular Weights of Acrylonitrile/Styrene Copolymers," and "Analytical Method for 10% Solution Viscosity of Tyril," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), 200 C Street SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

[2] As determined by the method titled "Headspace Sampling and Gas-Solid Chromatographic Determination of Residual Acrylonitrile in Acrylonitrile Copolyemr Solutions," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), 200 C Street SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

[3] As determined on appropriately shaped test samples of the article or acrylonitrile copolymer layer in a multilayer construction by ASTM method D-1434-82, "Standard Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), 200 C Street SW., Washington, DC 20204, and the American Society for

Testing Materials, 1916 Race Street, Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

(d) *Interim listing.* Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(e) Acrylonitrile copolymer identified in this section may be used to fabricate beverage containers only if they comply with the specifications of item 3 in paragraph (c) of this section.

(Secs. 201(s), 402, 52 Stat. 1046-1047 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342))

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48543, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 49 FR 36643, Sept. 19, 1984]

§ 177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.

Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer identified in this section may be safely used as a component of bottles intended for use with foods identified in Table I of § 176.170(c) of this chapter as Type VI-B under conditions for use E, F, or G described in Table 2 of § 176.170(c) of this chapter.

(a) *Identity.* For the purpose of this section, acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer consists of a blend of:

(1) 82-88 parts by weight of a matrix copolymer produced by polymerization of 77-82 parts by weight of acrylonitrile and 18-23 parts of styrene; and

(2) 12-18 parts by weight of a grafted rubber consisting of (i) 8-12 parts of butadiene/styrene elastomer containing 77-82 parts by weight of butadiene and 18-23 parts by weight of styrene and (ii) 4-6 parts by weight of a graft copolymer consisting of 70-77 parts by weight of acrylonitrile and 23-30 parts by weight of styrene.

(b) *Adjuvants.* The modified copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

Substances	Limitations
n-Dodecylmercaptan	The finished copolymer shall contain not more than 500 parts per million (ppm) dodecylmercaptan as dodecylmercapto-propionitrile as determined by the method titled, "Determination of β-Dodecyl-mercaptopropionitrile in NR-16 Polymer," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC 20408.

(c) *Specifications.* (1) Nitrogen content of the modified copolymer is in the range of 17.7-19.8 percent.

(2) Intrinsic viscosity of the matrix copolymer in butyrolactone is not less than 0.5 deciliter/gram at 35° C, as determined by the method titled "Molecular Weight of Matrix Copolymer by Solution Viscosity," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Residual acrylonitrile monomer content of the modified copolymer articles is not more than 11 ppm as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *Extractives limitations.* The following extractives limitations are determined by an infrared spectrophotometric method titled "Infrared Spectrophotometric Determination of Polymer Extracted from Borex® 210 Resin Pellets," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408, and are applicable to the modified copolymers in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10:

(1) The extracted copolymer shall not exceed 2.0 ppm in aqueous extract obtained when a 100-gram sample of copolymer is extracted with 250 milliliters of freshly distilled water at reflux temperature for 2 hours.

(2) The extracted copolymer shall not exceed 0.5 ppm in *n*-heptane when a 100-gram sample of the basic copolymer is extracted with 250 milliliters spectral grade *n*-heptane at reflux temperature for 2 hours.

(e) *Accelerated extraction end test.* The modified copolymer shall yield acrylonitrile monomer not in excess of 0.4 ppm when tested as follows:

(1) The modified copolymer shall be in the form of eight strips ¼ inch by 4 inches by .03 inch.

(2) The modified copolymer strips shall be immersed in 225 milliliters of 3 percent acetic acid in a Pyrex glass pressure bottle.

(3) The pyrex glass pressure bottle is then sealed and heated to 150° F in either a circulating air oven or a thermostat controlled bath for a period of 8 days.

(4) The Pyrex glass pressure bottle is then removed from the oven or bath and cooled to room temperature. A sample of the extracting solvent is then withdrawn and analyzed for acrylonitrile monomer by a gas chromatographic method titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies, are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(f) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(g) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

(Secs. 201(s), 402, 52 Stat. 1046-1047 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342))

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48544, Sept. 23, 1977; 47 FR 11841, Mar. 19, 1982; 47 FR 16775, Apr. 20, 1982]

§ 177.1200 Cellophane.

Cellophane may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Cellophane consists of a base sheet made from regenerated cellulose to which have been added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in this part, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances for which prior approval or sanctions permit their use in cellophane, under conditions specified in such sanctions and substances listed in § 181.22 of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of cellophane.

(4) Substances named in this section and further identified as required.

(c) List of substances:

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Acrylonitrile-butadiene copolymer resins	As the basic polymer.
Acrylonitrile-butadiene-styrene copolymer resins	Do.
Acrylonitrile-styrene copolymer resins	Do.
Acrylonitrile-vinyl chloride copolymer resins	Do.
N-Acyl sarcosines where the acyl group is lauroyl or stearoyl	For use only as release agents in coatings at levels not to exceed a total of 0.3 percent by weight of the finished packaging cellophane.
Alkyl ketene dimers identified in § 176.120 of this chapter	
Aluminum hydroxide	
Aluminum silicate	
Ammonium persulfate	
Ammonium sulfate	
Behenamide	
Butadiene-styrene copolymer	As the basic polymer.
1,3-Butanediol	
n-Butyl acetate	0.1 percent.
n-Butyl alcohol	Do.
Calcium ethyl acetoacetate	
Calcium stearoyl-2-lactylate identified in § 172.844 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Carboxymethyl hydroxyethylcellulose polymer	
Castor oil, hydrogenated	
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester.	As the basic polymer.
Castor oil phthalate, hydrogenated	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Castor oil, sulfonated, sodium salt	
Cellulose acetate butyrate	
Cellulose acetate propionate	
Cetyl alcohol	
Clay, natural	
Coconut oil fatty acid (C_{12}–C_{18}) diethanolamide, coconut oil fatty acid (C_{12}–C_{18}) diethanolamine soap, and diethanolamine mixture having total alkali (calculated as potassium hydroxide) of 16–18% and having an acid number of 25–35.	For use only as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Copal resin, heat processed.	As basic resin.
Damar resin	
Defoaming agents identified in § 176.200 of this chapter	
Dialkyl ketones where the alkyl groups are lauryl or stearyl	Not to exceed a total of 0.35 percent.
Dibutylphthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Dicyclohexyl phthalate	Do.
Diethylene glycol ester of the adduct of terpene and maleic anhydride.	
Di(2-ethylhexyl) adipate	
Di(2-ethylhexyl) phthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Diisobutyl phthalate	Do.
Dimethylcyclohexyl phthalate	Do.
Dimethyldialkyl (C_8–C_{18}) ammonium chloride	0.005 percent for use only as a flocculant for slip agents.
Di-*n*-ocyltin bis (2-ethylhexyl maleate)	For use only as a stabilizer at a level not to exceed 0.55 percent by weight of the coating solids in vinylidene chloride copolymer waterproof coatings prepared from vinylidene chloride copolymers identified in this paragraph, provided that such vinylidene chloride copolymers contain not less than 90 percent by weight of polymer units derived from vinylidene chloride.
N,N'-Dioleoyethylenediamine, N,N'-dilinoleoylethylene-diamine and N-oleoyl-N'linoleoylethylene-diamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°–228° F., as determined by ASTM method D127–60 ("Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax" (Revised 1960), which is incorporated by reference; copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and an acid value of 10 maximum.	0.5 percent.
N,N'-Dioleoylethylenediamine (*N,N'*-ethylenebisoleamide)	
Disodium EDTA	

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Distearic acid ester of di(hydroxyethyl) diethylenetriamine monoacetate.	0.06 percent.
N,N'-Distearoylethylenediamine (*N,N'*-ethylenebis stearamide)	
Epoxidized polybutadiene	For use only as a primer subcoat to anchor surface coatings to the base sheet.
Erucamide	
Ethyl acetate	
Ethylene-vinyl acetate copolymers complying with § 177.1350	
2-Ethylhexyl alcohol	0.1 percent for use only as lubricant.
Fatty acids derived from animal and vegetable fats and oils, and the following salts of such acids, single or mixed: Aluminum, ammonium, calcium, magnesium, potassium, sodium.	
Ferrous ammonium sulfate	
Fumaric acid	
Glycerin-maleic anhydride	As the basic polymer.
Glycerol diacetate	
Glycerol monoacetate	
Hydroxyethyl cellulose, water-insoluble	
Hydroxypropyl cellulose identified in § 172.870 of this chapter	
Isopropyl acetate	Residue limit 0.1 percent
Isopropyl alcohol	Do.
Itaconic acid	
Lanolin	
Lauryl alcohol	
Lauryl sulfate salts: ammonium, magnesium, potassium, sodium.	
Maleic acid	1 percent.
Maleic acid adduct of butadienestyrene copolymer	
Melamine formaldehyde	As the basic polymer.
Melamine-formaldehyde modified with one or more of the following: Butyl alcohol, diaminopropane, diethylenetriamine, ethyl alcohol, guanidine, imino-bis-butylamine, imino-bis-ethylamine, imino-bis-propylamine, methyl alcohol, polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane, sulfanilic acid, tetraethylenepentamine, triethanolamine, triethylenetetramine.	As the basic polymer, and used as a resin to anchor coatings to substrate.
Methyl ethyl ketone	Residue limit 0.1 percent
Methyl hydrogen siloxane	0.1 percent as the basic polymer.
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).	
Mineral oil, white	
Naphthalenesulfonic acid-formaldehyde condensate, sodium salt.	0.1 percent, for use only as an emulsifier.
Nitrocellulose, 10.9 percent–12.2 percent nitrogen	
Nylon resins complying with § 177.1500	
n-Octyl alcohol	For use only as a defoaming agent in the manufacture of cellophane base sheet.
Olefin copolymers complying with § 177.1520	
Oleic acid reacted with *N*-alkyl trimethylenediamine (alkyl C_{16} to C_{18}).	
Oleic acid, sulfonated, sodium salt	
Oleyl palmitamide	
N,N'-Oleoyl-stearylethylenediamine (*N*-(2-stearoylaminoethyl)oleamide).	
Paraffin, synthetic, complying with § 175.250 of this chapter	
Pentaerythritol tetrastearate	0.1 percent.
Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine as the basic resin.	For use only in cellophane coatings that contact food at temperatures not to exceed room temperature.
Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent monomer acids), ethylenediamine, and 4,4-bis(4-hydroxyphenyl)pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins).	As the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.
Polybutadiene resin (molecular weight range 2,000–10,200; bromine number range 210–320).	For use only as an adjuvant in vinylidene chloride copolymer coatings.
Polycarbonate resins complying with § 177.1580	

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride, and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70° C–92° C, and a color of K or paler.	
Polyethylene	
Polyethyleneaminostearamide ethyl sulfate produced when stearic acid is made to react with equal parts of diethylenetriamine and triethylenetetramine and the reaction product is quaternized with diethyl sulfate.	0.1 percent.
Polyethylene glycol (400) monolaurate	
Polyethylene glycol (600) monolaurate	
Polyethylene glycol (400) monooleate	
Polyethylene glycol (600) monooleate	
Polyethylene glycol (400) monostearate	
Polyethylene glycol (600) monostearate	
Polyethylene, oxidized: complying with the identity prescribed in § 177.1620(a).	
Polyethylenimine	As the basic polymer, for use as a resin to anchor coatings to the substrate and for use as an impregnant in the food-contact surface of regenerated cellulose sheet in an amount not to exceed that required to improve heat-sealable bonding between coated and uncoated sides of cellophane.
Polyisobutylene complying with § 177.1420	
Polyoxypropylene-polyoxyethylene block polymers (molecular weight 1,900–9,000).	For use as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Polypropylene complying with § 177.1520	
Polystyrene	As the basic polymer.
Polyvinyl acetate	Do.
Polyvinyl alcohol (minimum viscosity of 4 percent aqueous solution at 20° C of 4 centipoises)	
Polyvinyl chloride	As the basic polymer.
Polyvinyl stearate	Do.
n-Propyl acetate	Residue limit 0.1 percent.
n-Propyl alcohol	Do.
Rapeseed oil, blown	
Rosins and rosin derivatives as provided in § 178.3870 of this chapter.	
Rubber, natural (natural latex solids)	
Silica	
Silicic acid	
Sodium *m*-bisulfite	
Sodium dioctyl sulfosuccinate	
Sodium dodecylbenzenesulfonate	
Sodium lauroyl sarcosinate	0.35 percent; for use only in vinylidene chloride copolymer coatings.
Sodium oleyl sulfate-sodium cetyl sulfate mixture	For use only as an emulsifier for coatings; limit 0.005 percent where coating is applied to one side only and 0.01 percent where coating is applied to both sides.
Sodium silicate	
Sodium stearoyl-2-lactylate identified in § 172.846 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Sodium sulfate	
Sodium sulfite	
Spermaceti wax	
Stannous oleate	
2-Stearamido-ethyl stearate	
Stearyl alcohol	
Styrene-maleic anhydride resins	As the basic polymer.
Terpene resins identified in § 172.615 of this chapter	
Tetrahydrofuran	Residue limit of 0.1 percent.
Titanium dioxide	
Toluene	Residue limit of 0.1 percent.
Toluene sulfonamide formaldehyde	0.6 percent as the basic polymer.
Triethylene glycol	
Triethylene glycol diacetate, prepared from triethylene glycol containing not more than 0.1 percent of diethylene glycol.	

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
2,2,4-Trimethyl-1,3 pentanediol diisobutyrate	For use only in cellophane coatings and limited to use at a level not to exceed 10 percent by weight of the coating solids except when used as provided in § 178.3740 of this chapter
Urea (carbamide)	
Urea formaldehyde	As the basic polymer.
Urea formaldehyde modified with methanol, ethanol, butanol diethylenetriamine, triethylenetetramine, tetraethylenepentamine, guanidine, sodium sulfite, sulfanilic acid imino-bis-ethylamine, imino-bis-propylamine, imino-bis-butylamine, diaminopropane, diaminobutane, aminomethylsulfonic acid, polyamines made by reacting ethylenediamine or trimethylenediamine with dichlorethane or dichloropropane.	As the basic polymer, and used as a resin to anchor coatings to the substrate.
Vinyl acetate-vinyl chloride copolymer resins	As the basic polymer.
Vinyl acetate-vinyl chloride-maleic acid copolymer resins	Do.
Vinylidene chloride copolymerized with one or more of the following: Acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, 2-ethylhexyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride.	Do.
Vinylidene chloride-methacrylate decyloctyl copolymer	Do.
Wax, petroleum, complying with § 178.3710 of this chapter	

(d) Any optional component listed in this section covered by a specific food additive regulation must meet any specifications in that regulation.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11842, Mar. 19, 1982]

§ 177.1210 Closures with sealing gaskets for food containers.

Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Closures for food containers are manufactured from substances generally recognized as safe for contact with food; substances that are subject to the provisions of prior sanctions; substances authorized by regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; and closure-sealing gaskets, as further prescribed in this section.

(b) Closure-sealing gaskets and overall discs are formulated from substances identified in § 175.300(b) of this chapter, with the exception of paragraph (b)(3) (v), (xxxi), and (xxxii) of that section, and from other optional substances, including the following:

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval within the meaning of section 201(s) of the act.

(3) Substances that are the subject of regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter and used in accordance with the conditions prescribed.

(4) Substances identified in paragraph (b)(5) of this section, used in amounts not to exceed those required to accomplish the intended physical or technical effect and in conformance with any limitation provided; and further provided that any substance employed in the production of closure-sealing gasket compositions that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the identity or specifications prescribed.

(5) Substances that may be employed in the manufacture of closure-sealing gaskets include:

TABLE 1

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Arachidy-l-behenyl amide (C_{20}-C_{22}fatty acid amides)	5 percent.
Azodicarbonamide	1 2 percent. 2 5 percent, for use only in the manufacture of polyethylene complying with item 2.1 in § 177.1520(c) of this chapter.
Balata rubber	
Benzyl alcohol	1 percent.
1,3-Butanediol	
Calcium tin stearate	2 percent.
Calcium zinc stearate	Do.
Carbon, activated	1 percent.
Castor oil, hydrogenated	2 percent.
Chlorinated isobutylene-isoprene copolymers complying with § 177.1420.	
Coco amide (coconut oil fatty acids amides)	2 percent.
Cork (cleaned, granulated)	
Diebenzamide phenyl disulfide	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Di(C_7, C_9-alkyl) adipate	Complying with § 178.3740 of this chapter; except that, there is no limitation on polymer thickness.
Di-2-ethylhexyl adipate	
Di-2-ethylhexyl sebacate	2 percent.
Dihexyl ester of sodium sulfosuccinate	1 percent.
Diisodecyl phthalate	No limitation on amount used but for use only in closure-sealing gasket compositions used in contact with non-fatty foods containing no more than 8 percent of alcohol.
Di-*β*-naphthyl-*p*-phenylenediamine	1 percent.
Dipentamethylenethiurametetrasulfide	0.4 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Eicosane (technical grade) (water-white mixture of predominantly straight-chain paraffin hydrocarbons averaging 20 carbon atoms per molecule).	
Epoxidized linseed oil	
Epoxidized linseed oil modified with trimellitic anhydride	
Epoxidized safflower oil	
Epoxidized safflower oil modified with trimellitic anhydride	
Epoxidized soybean oil modified with trimellitic anhydride	
Erucylamide	5 percent.
Ethylene-propylene copolymer	
Ethylene-propylene modified copolymer elastomers produced when ethylene and propylene are copolymerized with 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene. The finished copolymer elastomers so produced shall contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene, and shall have a minimum viscosity average molecular weight of 120,000 as determined by the method described in § 177.1520(d)(5), and a minimum Mooney viscosity of 35 as determined by the method described in § 177.1520(d)(6).	
Ethylene-vinyl acetate copolymer	
Glyceryl mono-12-hydroxystearate (hydrogenated glyceryl ricinoleate).	2 percent.
Gutta-percha	
Hexamethylenetetramine	1 percent.
Hexylene glycol	0.5 percent.
Isobutylene-isoprene copolymers complying with § 177.1420	
Maleic anhydride-polyethylene copolymer	5 percent.
Maleic anhydride-styrene copolymer	Do.
2,2′-Methylenebis[6-(1-methylcylcohexyl)-*p*-cresol]	1 percent.
Napthalene sulfonic acid-formaldehyde condensate, sodium salt.	0.2 percent.
Natural rubber (crepe, latex, mechanical dispersions)	
α-*cis*-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles.	0.5 percent.
Oleyl alcohol	1 percent.
4,4′-Oxybis (benzene sulfonyl hydrazide)	0.5 percent.
Paraformaldehyde	1 percent.
Polybutadiene	

TABLE 1—Continued

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Poly-*p*-dinitroso benzene (activator for butyl rubber)	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Polyethylene glycol 400 esters of fatty acids derived from animal and vegetable fats and oils.	1 percent.
Polyisobutylene complying with § 177.1420	
Polyoxypropylene-polyoxyethylene condensate, average mol. wt. 2750–3000.	0.05 percent.
Potassium benzoate	1 percent.
Potassium perchlorate	Do.
Potassium propionate	2 percent.
Potassium and sodium persulfate	1 percent.
Resorcinol	0.24 percent; for use only as a reactive adjuvant substance employed in the production of gelatin-bonded cork compositions for use in lining crown closures. The gelatin so used shall be technical grade or better.
Rosins and rosin derivatives as defined in § 175.300(b)(3)(v) of this chapter for use only in resinous and polymeric coatings on metal substrates; for all other uses as defined in § 178.3870 of this chapter.	
Sodium cetyl sulfate	1 percent.
Sodium decylbenzenesulfonate	Do.
Sodium decyl sulfate	Do.
Sodium formaldehyde sulfoxylate	0.05 percent.
Sodium lauryl sulfate	1 percent.
Sodium lignin sulfonate	0.2 percent.
Sodium myristyl sulfate (sodium tetradecyl sulfate)	0.6 percent.
Sodium nitrite	0.2 percent; for use only in annular ring gaskets applied in aqueous dispersions to closures for containers having a capacity of not less than 5 gallons.
Sodium *o*-phenylphenate	0.05 percent.
Sodium polyacrylate	5 percent.
Sodium and potassium pentachlorophenate	0.05 percent.
Sodium salt of trisopropyl napthalenesulfonic acid	0.2 percent.
Sodium tridecylsulfate	0.6 percent.
Stearic acid amide	5 percent.
Sulfur	For use only as a vulcanizing agent in vulcanized natural or synthetic rubber gasket compositions at a level not to exceed 4 percent by weight of the elastomer content of the rubber gasket composition.
Tallow, sulfated	1 percent.
Tin-zinc stearate	2 percent.
Tri(mixed mono- and dinonylphenyl) phosphite	1 percent.
Vinyl chloride-vinyl stearate copolymer	
Zinc dibutyldithiocarbamate	0.8 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.

TABLE 2—MAXIMUM EXTRACTIVES TOLERANCES

[In parts per million]

Type of closure-sealing gasket composition	Chloroform fraction of water extractives	Chloroform fraction of heptane extractives	Chloroform fraction of alcohol extractives
1. Plasticized polymers, including unvulcanized or vulcanized or otherwise cured natural and synthetic rubber formed in place as overall discs or annular rings from a hot melt, solution, plastisol, organisol, mechanical dispersion, or latex	50	500	50

Type of closure-sealing gasket composition	Chloroform fraction of water extractives	Chloroform fraction of heptane extractives	Chloroform fraction of alcohol extractives
2. Preformed overall discs or annular rings of plasticized polymers, including unvulcanized natural or synthetic rubber	50	250	50
3. Preformed overall discs or annular rings of vulcanized plasticized polymers, including natural or synthetic rubber	50	50	50
4. Preformed overall discs or annular rings of polymeric or resinous-coated paper, paperboard, plastic, or metal foil substrates	50	250	50
5. Closures with sealing gaskets or sealing compositions as described in 1, 2, 3, and 4, and including paper, paperboard, and glassine used for dry foods only	(1)	(1)	(1)

(1) Extractability tests not applicable.

(c) The closure assembly to include the sealing gasket or sealing compound, together with any polymeric or resinous coating, film, foil, natural cork, or glass that forms a part of the food-contact surface of the assembly, when extracted on a suitable glass container with a solvent or solvents characterizing the type of foods, and under conditions of time and temperature characterizing the conditions of its use as determined from Tables 3 and 4 shall yield net chloroform-soluble extractives (corrected for zinc as zinc oleate) not to exceed the tolerances specified in Table 2, calculated on the basis of the water capacity of the container on which the closure is to be used. Employ the analytical method described in § 175.300 of this chapter, adapting the procedural details to make the method applicable to closures; such as, for example, placing the closed glass container on its side to assure contact of the closure's food-contacting surface with the solvent.

TABLE 3—TYPES OF FOOD

I. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
II. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
IV. Dairy products and modifications:
  A. Water-in-oil emulsions, high- or low-fat.
  B. Oil-in-water emulsions, high- or low-fat.
V. Low-moisture fats and oils.
VI. Beverages:
  A. Containing alcohol.
  B. Nonalcoholic.
VII. Bakery products.
VIII. Dry solids (no end-test required).

TABLE 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Conditions of use	Types of food (see Table 3)	Extractant		
		Water[2]	Heptane[1,2]	8 percent alcohol[2]
A. High temperature heat-sterilized (e.g., over 212° F).	I, IV-B	250° F, 2 hr		
	III, IV-A, VII	do	150° F, 2 hr	
B. Boiling water-sterilized	II	212° F, 30 min		
	III, VII	do	120° F, 30 min	
C. Hot filled or pasteurized above 150° F.	II, IV-B	Fill boiling, cool to 100° F.		
	III, IV-A	do	120° F, 15 min	
	V		do	
D. Hot filled or pasteurized below 150° F.	II, IV-B, VI-B	150° F, 2 hr		
	III, IV-A	do	100° F, 30 min	
	V		do	
	VI-A			150° F, 2 hr.

TABLE 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES—Continued

Conditions of use	Types of food (see Table 3)	Extractant		
		Water [2]	Heptane [1] [2]	8 percent alcohol [2]
E. Temperature filled and stored (no thermal treatment in the container).	II, IV-B, VI-B	120° F, 24 hr		
	III, IV-A	do	70° F, 30 min	
	V		do	
	VI-A			120° F, 24 hr.
F. Refrigerated storage (no thermal treatment).	I, II, III, IV-A, IV-B, VI-B, VII.	70° F, 48 hr	70° F, 30 min	
	VI-A			70° F, 48 hr.
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII	70° F, 24 hr		

[1] Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.

[2] Time and temperature.

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977; 47 FR 22090, May 21, 1982; 49 FR 5748, Feb. 15, 1984]

§ 177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.

Copolymer of 1,4-cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate may be safely used as an article or component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The copolymer is a basic polyester produced by the catalytic condensation of dimethyl terephthalate and dimethyl isophthalate with 1,4-cyclohexanedimethanol, to which may have been added certain optional substances required in its production or added to impart desired physical and technical properties.

(b) The quantity of any optional substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of the copolymer that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of the copolymer include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in the copolymer and used in accordance with such sanction or approval.

(3) Substances which by regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter may be safely used as components of resinous or polymeric coatings and film used as food-contact surfaces, subject to the provisions of such regulation.

(e) The copolymer conforms with the following specifications:

(1) The copolymer, when extracted with distilled water at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

(2) The copolymer, when extracted with ethyl acetate at reflux temperature for 2 hours, yields total extractives not to exceed 0.7 percent.

(3) The copolymer, when extracted with *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984]

§ 177.1310 Ethylene-acrylic acid copolymers.

The ethylene-acrylic acid copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for use in contact with food subject to the provisions of this section.

(a) The ethylene-acrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and acrylic acid such that the finished basic copolymers contain no more than:

(1) 10 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (b) of this section; and

(2) 25 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (c) of this section.

(b) The finished food-contact articles made with no more than 10 percent total polymer units derived from acrylic acid, when extracted with the solvent or solvents characterizing the type of food and under the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yield net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods prescribed in § 177.1330(c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with § 176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in § 176.170(d)(5)(iii)(*b*) of this chapter. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.

(c) The finished food-contact layer made with basic copolymers containing more than 10 weight-percent but no more than 25 weight-percent of total polymer units derived from acrylic acid and with a maximum thickness of 0.0025 inch (2.5 mils) may be used in contact with food types I, II, IVB, VIA, VIB, VIIB, and VIII identified in table 1 of § 176.170(c) of the chapter under conditions of use B through H as described in table 2 of § 176.170(c) of this chapter, and in contact with food types III, IVA, V, VIIA, and IX identified in table 1 of § 176.170(c) of this chapter under conditions of use E through G as described in table 2 of § 176.170(c) of this chapter.

(d) The provisions of this section are not applicable to ethylene-acrylic acid copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 51 FR 19060, May 27, 1986]

§ 177.1315 Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.

Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymer may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and of Part 174 of this chapter.

(a) *Identity.* For the purposes of this section, ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers (1,4-benzene dicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25640-14-6) or (1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25038-91-9) are basic copolymers meeting the specifications prescribed in paragraph (b) of this section, to which may have been added certain optional substances required in their production or added to impart desired physical or technical properties.

(b) *Specifications:*

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
1. *Non-oriented* ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 66 mole percent of ethylene glycol and 1 to 34 mole percent of 1,4-cyclo-hexanedimethanol (70 percent *trans* isomer, 30 percent *cis* isomer).	Inherent viscosity of a 0.50 percent solution of the copolymer in phenol-tet rachloroethane (60:40 ratio wt/wt) solvent is not less than 0.669 as determined by using a Wagner viscometer (or equivalent) and calculated from the following equation: Inherent viscosity=(Natural logarithm of (N_r)/(c) where: N_r=Ratio of flow time of the polymer solution to that of the solvent, and c=concentration of the test solution expressed in grams per 100 milliliters.	(1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with water added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120°F) in contact with the food-contact article.	No test required	In contact with foods, including foods containing not more than 25 percent (by volume) aqueous alcohol, excluding carbonated beverages and beer. Conditions of hot fill not to exceed 82.2 °C (180 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container.
	do	(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with 3 percent (by volume) aqueous acetic acid added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	do	Do.
	do	(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface when extracted for 2 hours with *n*-heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5.	do	Do.
	do	(4) 0.16 microgram per square centimeter (1.0 microgram per square inch) of food-contact surface when extracted for 24 hours with 25 percent (by volume) aqueous ethanol at 48.9 °C (120 °F).	do	Do.

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Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
2. *Oriented* ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 85 mole percent ethylene glycol and 1 to 15 mole percent of 1,4-cyclohexane-di-methanol (70 percent *trans* isomer, 30 percent *cis* isomer).	......do......................................	(1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of the oriented copolymer when extracted with water added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	When extracted with heptane at 65.6 °C (150 °F) for 2 hours: terephthaloyl moieties do not exceed 0.09 microgram per square centimeter (0.60 microgram per square inch) of food-contact surface.	In contact with nonalcoholic foods including carbonated beverages. Conditions of hot fill not exceeding 87.8 °C (190 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container.
	......do......................................	(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 3 percent (by volume) aqueous acetic acid added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article..	......do......................................	Do.
	......do......................................	(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface of oriented copolymer when extracted for 2 hours with *n*-heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5.	......do......................................	Do.
	......do......................................	(4) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 20 percent (by volume) aqueous ethanol heated to 65.6 °C (150 °F) for 20 minutes and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	......do......................................	In contact with foods and beverages containing up to 20 percent (by volume) alcohol. Conditions of thermal treatment in the container not exceeding 65.6 °C (150 °F) for 20 minutes. Storage at temperatures not in excess of 48.9 °C (120 °F).

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	......do......	(5) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 50 percent (by volume) aqueous ethanol at 48.9 °C (120 °F) for 24 hours.	......do......	In contact with foods and beverages containing up to 50 percent (by volume) alcohol. Conditions of fill and storage not exceeding 48.9 °C (120 °F). No thermal treatment in the container.

(c) *Analytical method for determination of extractability.* The total extracted terephthaloyl moieties can be determined in the extracts, without evaporation of the solvent, by measuring the ultraviolet (UV) absorbance at 240 nanometers. The spectrophotometer (Varian 635-D, or equivalent) is zeroed with a sample of the solvent taken from the same lot used in the extraction tests. The concentration of the total terephthaloyl moieties in water, 3 percent acetic acid, and in 8 percent aqueous alcohol is calculated as bis(2-hydroxyethyl terephthalate) by reference to standards prepared in the appropriate solvent. Concentration of the terephthaloyl moieties in heptane is calculated as cyclic trimer $(C_6H_4CO_2C_2H_4CO_2)_3$, by reference to standards prepared in 95:5 percent (v/v) heptane: tetrahydrofuran.

[45 FR 39252, June 10, 1980, as amended at 47 FR 24288, June 4, 1982; 49 FR 25629, June 22, 1984; 51 FR 22929, June 24, 1986]

§ 177.1320 Ethylene-ethyl acrylate copolymers.

Ethylene-ethyl acrylate copolymers may be safely used to produce packaging materials, containers, and equipment intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Ethylene-ethyl acrylate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and ethyl acrylate, to which may have been added certain optional substances to impart desired technological properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in Parts 170 through 189 of this chapter, prior sanction, or approvals.

(b) The ethyl acrylate content of the copolymer does not exceed 8 percent by weight unless it is blended with polyethylene or with one or more olefin copolymers complying with § 177.1520 or with a mixture of polyethylene and one or more olefin copolymers, in such proportions that the ethyl acrylate content of the blend does not exceed 8 percent by weight, or unless it is used in a coating complying with § 175.300 or § 176.170 of this chapter, in such proportions that the ethyl acrylate content does not exceed 8 percent by weight of the finished coating.

(c) Ethylene-ethyl acrylate copolymers or the blend shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the ethyl acrylate content limits prescribed in paragraph (b) of this section, and the extractability limits prescribed in paragraph (c)(2) of this section, when tested by the methods prescribed for polyethylene in § 177.1520.

(1) *Specifications*—(i) *Infrared identification.* Ethylene-ethyl acrylate copolymers can be identified by their characteristic infrared spectra.

(ii) *Quantitative determination of ethyl acrylate content.* The ethyl acrylate can be determined by the infrared spectra. Prepare a scan from 10.5 microns to 12.5 microns. Obtain a baseline absorbance at 11.6 microns and divide by the plaque thickness to obtain absorbance per mil. From a previously prepared calibration curve, obtain the amount of ethyl acrylate present.

(iii) *Specific gravity.* Ethylene-ethyl acrylate copolymers have a specific gravity of not less than 0.920 nor more than 0.935, as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Limitations.* Ethylene-ethyl acrylate copolymers or the blend may be used in contact with food except as a component of articles used for packaging or holding food during cooking provided they meet the following extractability limits:

(i) Maximum soluble fraction of 11.3 percent in xylene after refluxing and subsequent cooling to 25° C.

(ii) Maximum extractable fraction of 5.5 percent when extracted with *n*-hexane at 50° C.

(d) The provisions of paragraphs (b) and (c)(2) of this section are not applicable to ethylene-ethyl acrylate copolymers used in the formulation of adhesives complying with § 175.105 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784–1788 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10108, Mar. 19, 1984]

§ 177.1330 Ionomeric resins.

Ionomeric resins manufactured from either ethylene-methacrylic acid copolymers (and/or their ammonium, calcium, magnesium, potassium, sodium, and/or zinc partial salts), ethylene-methacrylic acid-vinyl acetate copolymers (and/or their ammonium, calcium, magnesium, potassium, sodium, and/or zinc partial salts,), or methacrylic acid polymers with ethylene and isobutyl acrylate (and/or their potassium, sodium and/or zinc partial salts) may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the ethylene-methacrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and methacrylic acid such that the copolymers contain no more than 20 weight percent of polymer units derived from methacrylic acid, and the ethylene-methacrylic acid-vinyl acetate copolymers consist of basic copolymers produced by the copolymerization of ethylene, methacrylic acid, and vinyl acetate such that the copolymers contain no more than 15 weight percent of polymer units derived from methacrylic acid.

(b) For the purpose of this section, the methacrylic acid copolymers with ethylene and isobutyl acrylate consist of basic copolymers produced by the copolymerization of methacrylic acid, ethylene, and isobutyl acrylate such that the copolymers contain no less than 70 weight percent of polymer units derived from ethylene, no more than 15 weight percent of polymer units derived from methacrylic acid, and no more than 20 weight percent of polymer units derived from isobutyl acrylate. From 20 percent to 70 percent of the carboxylic acid groups may optionally be neutralized to form sodium or zinc salts.

(c) The finished food-contact article described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields net acidified chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in paragraph (l)(1) of this section, and if the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

(d) The finished food-contact article described in paragraph (b) of this section, when extracted according to the methods listed in paragraph (e)(2) of this section and referenced in this paragraph (d), using the solvent or solvents characterizing the type of food as determined from Table I of paragraph (f) of this section, shall yield net acidified chloroform-soluble extractives as follows:

(1) *For fatty food use.* (i) For films of 2 mil (0.002 inches) thickness or less, extractives shall not exceed 0.70 milligram/square inch[1] (0.109 milligram/square centimeter) of food-contact surface (*n*-heptane extractions) when extracted by the abbreviated method cited in paragraph (e)(2)(i) of this section.

(ii) For films of greater than 2 mils (0.002 inch) thickness, extractives shall not exceed 0.40 milligram/square inch[1] (0.062 milligram/square centimeter) of food-contact surface (*n*-heptane extractions) when extracted by the abbreviated method cited in paragraph (e)(2)(i) of this section, or

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[1] Average of four separate values, no single value of which differs from the average of those values by more then ±10 percent.

(iii) Alternatively, for films of greater than 2 mils thickness, extractives shall not exceed 0.70 milligram/square inch[1] (0.109 milligram/square centimeter) of food-contact surface (*n*-heptane extractions) when extracted by the equilibrium method cited in paragraph (e)(2)(ii) of this section.

(2) *For aqueous foods.* (i) The net acidified chloroform-soluble extractives shall not exceed 0.02 milligram/square inch[2] (0.003 milligram/square centimeter) of food-contact surface (water, acetic acid, or ethanol/water extractions) when extracted by the abbreviated method cited in paragraph (e)(2)(i) of this section.

(ii) Alternatively, the net acidified chloroform-soluble extractives shall not exceed 0.05 milligram/square inch[2] (0.078 mg/square centimeter) of food-contact surface (water, acetic acid, or ethanol/water extractions) when extracted by the equilibrium method cited in paragraph (e)(2)(ii) of this section. If when exposed to *n*-heptane, a particular film splits along die lines, thus permitting exposure of both sides of the film to the extracting solvent, the results for that film sample are invalid and the test must be repeated for that sample until no splitting by the solvent occurs. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

(e) *Analytical methods*—(1) *Selection of extractability conditions for ionomeric resins.* First ascertain the type of food (Table 1 of § 176.170(c) of this chapter) that is being packed or used in contact with the finished food-contact article described in paragraph (a) of this section, and also ascertain the normal conditions of thermal treatment used in packaging or contacting the type of food involved. Using Table 2 of § 176.170 (c) of this chapter, select the food-simulating solvent or solvents and the time-temperature test conditions that correspond to the intended use of the finished food-contact article. Having selected the appropriate food-simulating solvent or solvents and time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) *Selection of extractability conditions for ionomeric resins.* Using Table I of paragraph (f) of this section ascertain the type of food that is being packed or used in contact with the finished food-contact article described in paragraph (b) of this section, and also ascertain the food-simulating solvent or solvents that correspond to the intended use of the finished food-contact article.

(i) *Abbreviated test.* For intended use involving food contact at or below 120° F (49° C), the appropriate food-simulating solvent is to contact the food-contact film for the time and temperatures as follows:

Solvent	Time	Temperature
n-Heptane	[1] 2	120° F (49° C).
Water, 3% acetic acid, or 8%/50% ethanol	[1] 48	120° F (49° C).

[1] Hours

(ii) *Equilibrium test.* For intended use involving food contact at or below 120° F (49° C), the appropriate food-simulating solvent is to contact the food-contact film at a temperature of 120° F until equilibrium is demonstrated.

Solvent	Minimum extraction times (hours)
n-Heptane	8, 10, 12
Water, 3% acetic acid, or 8%/50% ethanol	72, 96, 120

The results from a series of extraction times demonstrate equilibrium when the net chloroform-soluble extractives are unchanging within experimental error appropriate to the method as described in paragraphs (d) (1)(i) and (2)(i) of this section. Should equilibrium not be demonstrated over the above time series, extraction times must be extended until three successive unchanging values for extractives are obtained. In the case where intended uses involve temporary food contact above 120° F, the food-simulating solvent is to be contacted with the food-contact article under conditions of time and temperature that duplicate the actual conditions in the intended use. Subsequently the extraction is to be continued for the time period and under the conditions specified in the above table.

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[2] Average of four separate values, no single value of which differs from the average of those values by more than ±50 percent.

(3) *Reagents*—(i) *Water.* All water used in extraction procedures should be freshly demineralized (deionized) distilled water.

(ii) *n-Heptane.* Reagent grade, freshly redistilled before use, using only material boiling at 208° F (97.8° C).

(iii) *Alcohol.* 8 or 50 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized (deionized), distilled water.

(iv) *Chloroform.* Reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

(v) *Acetic acid.* 3 percent (by weight), prepared from glacial acetic acid diluted with demineralized (deionized), distilled water.

(4) *Selection of test method.* The finished food-contact articles shall be tested either by the extraction cell described in the *Journal of the Association of Official Agricultural Chemists,* Vol. 47, No. 1, p. 177-179 (February 1964), also described in ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which are incorporated by reference, or by adapting the in-container methods described in § 175.300(e) of this chapter. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, respectively, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(5) *Selection of samples.* Quadruplicate samples should be tested, using for each replicate sample the number of finished articles with a food-contact surface nearest to 100 square inches.

(6) *Determination of amount of extractives*—(i) *Total residues.* At the end of the exposure period, remove the test container or test cell from the oven, if any, and combine the solvent for each replicate in a clean Pyrex (or equivalent) flask or beaker, being sure to rinse the test container or cell with a small quantity of clean solvent. Evaporate the food-simulating solvents to about 100 milliliters in the flask, and transfer to a clean, tared evaporating dish (platinum or Pyrex), washing the flask three times with small portions of solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking, low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 221° F (105° C). Cool the evaporating dish in a desiccator for 30 minutes and weigh the residues to the nearest 0.1 milligram, *e.* Calculate the extractives in milligrams per square inch of the container or material surface.

(*a*) *Water, 3 percent acetic acid, and 8 percent and 50 percent alcohol.* Milligrams extractives per square inch $=e/s$.

(*b*) *Heptane.* Milligrams extractives per square inch $=(e)/(s)(F)$

Where:

e = Milligrams extractives per sample tested.

s = Surface area tested, in square inches.

F = Five, the ratio of the amount of extractives removed by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil under exaggerated conditions of thermal sterilization and use.

e' = Acidified chloroform-soluble extractives residue. e' is substituted for e in the above equations when necessary (See paragraph (e)(6)(ii) of this section for method to obtain e').

If when calculated by the equations in paragraphs (e)(6)(i) (a) and (b) of this section, the extractives in milligrams per square inch exceed the limitations prescribed in paragraphs (c) or (d) of this section, proceed to paragraph (e)(6)(ii) of this section (method for determining the amount of acidified chloroform-soluble extractives residue).

(ii) *Acidified chloroform-soluble extractives residue.* Add 3 milliliters of 37 percent ACS reagent grade hydrochloric acid and 3 milliliters of distilled water to the evaporating dish containing the dried and weighed residue, *e*, obtained in paragraph (e)(6)(i) of this section. Mix well so every portion of the residue is wetted with the hydrochloric acid solution. Then add 50 milliliters of chloroform. Warm carefully, and filter through Whatman No. 41 filter paper (or equivalent) in a Pyrex (or equivalent) funnel, collecting the filtrate in a clean separatory funnel. Shake for 1 minute, then draw off the chloroform layer into a clean tared evaporating dish (platinum or Pyrex). Repeat the chloroform extraction, washing the dish, the filter paper, and the separatory funnel with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the acidified chloroform-soluble extractives residue, e'. This e' is substituted for *e* in the equations in paragraphs (e)(6)(i) (a) and (b) of this section.

(f) The types of food and appropriate solvents are as follows:

TABLE 1

Types of food	Appropriate solvent
1. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.	Water, *n*-heptane.
2. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.	*n*-heptane, water, 3% acetic acid.
3. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.	Water, *n*-heptane, 3% acetic acid.
4. Dairy products and modifications:	
Water, *n*-heptane	
i. Water-in-oil emulsions, high or low fat.	
ii. Oil-in-water emulsions, high or low fat.	
5. Low moisture fats and oils	*n*-heptane.
6. Beverages:	
i. Containing up to 8% alcohol	8% ethanol/water.
ii. Nonalcoholic	3% acetic acid.
iii. Containing more than 8% alcohol.	50% ethanol/water.
7. Bakery products	Water, *n*-heptane.
8. Dry solids (without free fat or oil).	No extraction test required.
9. Dry solids (with free fat or oil)	*n*-heptane.

(g) The provisions of paragraphs (c) and (d) of this section are not applicable to the ionomeric resins that are used in food-packaging adhesives complying with § 175.105 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376; secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[45 FR 22916, Apr. 4, 1980, as amended at 49 FR 10108, Mar. 19, 1984; 49 FR 37747, Sept. 26, 1984]

§ 177.1340 Ethylene-methyl acrylate copolymer resins.

Ethylene-methyl acrylate copolymer resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the ethylene-methyl acrylate copolymer resins consist of basic copolymers produced by the copolymerization of ethylene and methyl acrylate such that the copolymers contain no more than 25 weight percent of polymer units derived from methyl acrylate.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields net chloroform-soluble extractives (corrected for zinc extractives as zinc oleate) in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in § 176.170(d) of this chapter. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

(c) The provisions of this section are not applicable to ethylene-methyl acrylate copolymer resins used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1350 Ethylene-vinyl acetate copolymers.

Ethylene-vinyl acetate copolymers may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Ethylene-vinyl acetate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and vinyl acetate to which may have been added certain optional substances to impart desired technological or physical properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in Parts 170 through 189 of this chapter, prior sanction, or approvals.

(3) Substances identified in § 175.300(b)(3) (xxv), (xxvi), (xxvii), (xxx), and (xxxiii) of this chapter.

(4) Erucamide as identified in § 178.3860 of this chapter.

(5) Xanthan gum as identified in § 172.695 for use as a thickening agent at a level not to exceed 1 percent by weight of coating solids in aqueous dispersions of ethylene-vinyl acetate copolymers, where such copolymers are used only as coatings or a component of coatings.

(b) Ethylene-vinyl acetate copolymers, with or without the optional substances described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of their intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives corrected for zinc as zinc oleate not to exceed 0.5 milligram per square inch of an appropriate sample.

(c) The provisions of paragraph (b) of this section are not applicable to ethylene-vinyl acetate copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

(d) Ethylene-vinyl acetate copolymers may be irradiated under the following conditions to produce molecular crosslinking of the polymers to impart desired properties such as increased strength and increased ability to shrink when exposed to heat:

(1) Electron beam source of ionizing radiation at a maximum energy of 3 million electron volts: maximum absorbed dose not to exceed 8 megarads.

(2) The finished food-contact film shall meet the extractives limitations prescribed in paragraph (e)(2) of this section.

(3) The ethylene-vinyl acetate copolymer films may be further irradiated in accordance with the provisions of paragraph (e)(1) of this section: *Provided*, That the total accumulated radiation dose from both electron beam and gamma ray radiation does not exceed 8.0 megarads.

(e) Ethylene-vinyl acetate copolymer films intended for contact with food may be irradiated to control the growth of microorganisms under the following conditions:

(1) Gamma photons emitted from a cobalt-60 sealed source in the dose range of 0.5–5.0 megarads.

(2) The irradiated ethylene-vinyl acetate copolymer films, when extracted with reagent grade n-heptane (freshly redistilled before use) according to

methods described under § 176.170(d)(3) of this chapter, at 75° F for 30 minutes shall yield total extractives not to exceed 4.5 percent by weight of the film.

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 29287, July 7, 1978]

§ 177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.

Ethylene-vinyl acetate-vinyl alcohol copolymers (CAS Reg. No. 26221-27-2) may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Ethylene-vinyl acetate-vinyl alcohol copolymers are produced by the partial or complete alcoholysis or hydrolysis of those ethylene-vinyl acetate copolymers complying with § 177.1350.

(1) Those copolymers containing a minimum of 55 percent ethylene and a maximum of 30 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (b) of this section.

(2) Those copolymers containing a minimum of 55 percent ethylene and a maximum of 15 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (c) of this section.

(3) Those copolymers containing 20 to 40 percent ethylene and 60 to 80 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (d) of this section.

(b) The finished food-contact article shall not exceed 0.013 centimeter (0.005 inch) thickness and shall contact foods only of the types identified in Table 1 of § 176.170(c) of this chapter in Categories I, II, IV-B, VI, VII-B, and VIII under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter. Film samples of 0.013 centimeter (0.005) inch thickness representing the finished article shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(1) The film when extracted with distilled water at 21° C (70° F) for 48 hours yields total extractives not to exceed 0.0047 milligram per square centimeter (0.03 milligram per square inch) of food-contact surface.

(2) The film when extracted with 50 percent ethyl alcohol at 21° C (70° F) for 48 hours yields total extractives not to exceed 0.0062 milligram per square centimeter (0.04 milligram per square inch) of food-contact surface.

(c) The finished food-contact article shall not exceed 0.0076 centimeter (0.003 inch) thickness and shall contact foods only of the types identified in Table 1 of § 176.170(c) of this chapter in Categories III, IV-A, VII-A, and IX under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter. Film samples of 0.0076 centimeter (0.003 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with *n*-heptane at 38° C (100° F) for 30 minutes yields total extractives not to exceed 0.0078 milligram per square centimeter (0.05 milligram per square inch) of food-contact surface, after correcting the total extractives by dividing by a factor of five.

(d) The finished food-contact article shall not exceed 0.018 centimeter (0.007 inch) thickness and may contact all foods except those containing more than 8 percent alcohol under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. Film samples of 0.018 centimeter (0.007 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with distilled water at 100° C (212° F) for 30 minutes yields total extractives not to exceed 0.023 milligram per square centimeter (0.15 milligram per square inch) of food-contact surface.

(e) The provisions of this section are not applicable to ethylene-vinyl acetate-vinyl alcohol copolymers used in the food-packaging adhesives complying with § 175.105 of this chapter.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348; secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[47 FR 41531, Sept. 21, 1982, as amended at 49 FR 10108, Mar. 19, 1984]

§ 177.1380 Fluorocarbon resins.

Fluorocarbon resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, fluorocarbon resins consist of basic resins produced as follows:

(1) Chlorotrifluoroethylene resins produced by the homopolymerization of chlorotrifluoroethylene.

(2) Chlorotrifluoroethylene-1,1-difluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene and 1,1-difluoroethylene.

(3) Chlorotrifluoroethylene-1,1-difluoroethylene-tetrafluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene, 1,1-difluoroethylene, and tetrafluoroethylene.

(b) Fluorocarbon resins that are identified in paragraph (a) of this section and that comply with the extractives limitations prescribed in paragraph (c) of this section may be used as articles or components of articles intended for use in contact with food. Fluorocarbon resins that are identified in paragraph (a) of this section and that comply only with the extractives limitations prescribed in paragraphs (c) (1) and (2) of this section may be used when such use is limited to articles or components of articles that are intended for repeated use in contact with food or that are intended for one-time use in contact with food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types I, II, VI, VII-B and VIII. In accordance with good manufacturing practice, those food-contact articles intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

(c) Extractives limitations are applicable to the basic resins in the form of pellets that have been ground or cut into small particles that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10.

(1) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(2) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(3) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of *n*-heptane at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.01 percent by weight of the resins.

§ 177.1390 High-temperature laminates.

(a) The high-temperature laminates identified in this section may be safely used for food contact at temperatures not exceeding 135° C (275° F) unless otherwise specified. These articles are layered constructions that are optionally bonded with adhesives. The interior (food-contact) layer(s) may be separated from the exterior layer(s) by a functional barrier, such as aluminum foil. Upon review of the physical properties of a particular construction, the Food and Drug Administration may consider other layers to serve as functional barriers. This regulation is not intended to limit these constructions as to shape, degree of flexibility, thickness, or number of layers. These layers may be laminated, extruded, coextruded, or fused.

(b) When containers subject to this regulation undergo heat sterilization to produce shelf-stable foods, certain control measures (in addition to the food additive requirements in paragraphs (c) and (d) of this section) are necessary to ensure proper food sterilization and package integrity. Refer to Parts 108, 110, 113, and 114 of this chapter for details.

(c) Subject to the provisions of this paragraph, food-contact articles produced from high-temperature laminates may be safely used to package all food types except those containing more than 8 percent ethyl alcohol.

(1) *Polymeric films/layers.* Films or layers not separated from food by a functional barrier must meet the following requirements:

(i) Films/layers may consist of the following:

(*a*) Polyolefin resins complying with item 2.2 or 3.2 of the table in § 177.1520(c).

(*b*) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in § 177.1520(c) blended with no more than 10 percent by weight of a copolymer of ethylene and vinyl acetate complying with § 177.1350.

(*c*) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in § 177.1520(c) blended with no more than 38 percent by weight of a homopolymer of isobutylene complying with § 177.1420(a)(1).

(*d*) Polyethylene phthalate resins complying with § 177.1630(e)(4) (i) and (ii).

(*e*) Polymeric resins that comply with an applicable regulation in this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Adjuvants used in these layers must comply with an applicable regulation that permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(2) *Adhesives.* The use of adhesives in these containers is optional. Adhesives may be formulated from the following substances, subject to the prescribed limitations:

(i) Any substance suitable for use in formulating adhesives that complies with an applicable regulation of this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Substances complying with § 175.105 of this chapter may be used in these constructions, provided they are separated from the interior (food-contact) layer(s) by a functional barrier as discussed under paragraph (a) of this section.

(iii) Maleic anhydride adduct of polypropylene complying with § 175.300 of this chapter.

(iv) Polyester-urethane adhesive for use at temperatures not exceeding 121° C (250° F) and formulated from the following:

(*a*) Polyester-urethanediol resin prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in § 175.300(b)(3)(vii) of this chapter, 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) and optional trimethoxysilane coupling agents containing amino, epoxy, ether, and/or mercapto groups not to exceed 3 percent by weight of the cured adhesive.

(*b*) Urethane cross-linking agent comprising not more than 25 percent by weight of the cured adhesive and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) adduct of trimethylol propane (Cas Reg. No. 77-99-6) and/or 1,3-bis(isocyanatomethyl) benzene (CAS Reg. No. 25854-16-4) adduct of trimethylol propane.

(v) Polyester-epoxy-urethane adhesives formulated from the following:

(*a*) Polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in § 175.300(b)(3)(vii) of this chapter. Azelaic acid may also be used as a polybasic acid.

(*b*) Epoxy resin listed in § 175.300(b)(3)(viii)(*a*) of this chapter and comprising no more than 30 percent by weight of the cured adhesive.

(*c*) Urethane cross-linking agent comprising no more than 14 percent weight of the cured adhesive and formulated from 3-isocyanatomethyl-

3,5,5-trimethylcyclohexyl isocyanate cyanurate (CAS Reg. No. 53880-05-0).

(3) *Test specifications.* These specifications apply only to materials on the food-contact side of a functional barrier, if present. All tests must be performed on containers made under production conditions. Laminated structures submitted to extraction procedures must maintain complete structural integrity (particularly with regard to delamination) throughout the test.

(i) *Nonvolatile extractives.* (*a*) For use at temperatures not to exceed 121° C (250° F): The container interior (food-contact side) shall be extracted with deionized distilled water at 121° C (250° F) for 2 hours.

(*1*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraphs (c)(2) (i), (ii), (iii), and (iv) of this section shall not exceed 0.0016 milligram per square centimeter (0.01 milligram per square inch) as determined by a method titled "Determination of Nonvolatile Chloroform Soluble Residues in Retort Pouch Water Extractives," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20404, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(*2*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled "Determination of Nonvolatile Chloroform Soluble Residues in Retort Pouch Water Extractives," which is incorporated by reference in paragraph (c)(3)(i)(*a*)(*1*) of this section.

(*b*) For use at temperatures not to exceed 135° C (275° F): The container interior (food-contact side) shall be extracted with deionized distilled water at 135° C (275° F) for 1 hour.

(*1*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using no adhesive, or adhesives listed in paragraphs (c)(2) (i), (ii), and (iii) of this section shall not exceed 0.0020 milligram per square centimeter (0.013 milligram per square inch) as determined by a method titled "Determination of Nonvolatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(*a*)(*1*) of this section.

(*2*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled "Determination of Nonvolatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(*a*)(*1*) of this section.

(ii) *Volatiles.* Volatile substances employed in the manufacture of high-temperature laminates must be removed to the greatest extent possible in keeping with good manufacturing practice prescribed in § 174.5(a) of this chapter.

(d) Nylon 12/aluminum foil high-temperature laminates: Subject to the provisions of this paragraph, containers constructed of nylon 12 laminated to aluminum foil may be safely used at temperatures no greater than 250° F (121° C) in contact with all food types except those containing more than 8 percent alcohol.

(1) The container is constructed of aluminum foil to which nylon 12 film is fused. Prior to fusing the nylon 12, the aluminum foil may be optionally precoated with a coating complying with § 175.300 of this chapter.

(2) Nylon 12 resin complying with § 177.1500 and having an average thickness not to exceed 0.0016 inch (41 microns) may be used as the food-contact surface of the container.

(3) Container test specifications. On exposure to distilled water at 250° F (121° C) for 2 hours, extractives from the food-contact side of the nylon 12 multilayered construction shall not exceed 0.05 milligram per square inch

(0.0078 milligram per square centimeter) as total nonvolatile extractives.

[45 FR 2843, Jan. 15, 1980, as amended at 47 FR 49639, Nov. 2, 1982; 48 FR 236, Jan. 4, 1983; 48 FR 15242, Apr. 8, 1983; 48 FR 17347, Apr. 22, 1983; 49 FR 7558, Mar. 1, 1984]

§ 177.1400 Hydroxyethyl cellulose film, water-insoluble.

Water-insoluble hydroxyethyl cellulose film may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Water-insoluble hydroxyethyl cellulose film consists of a base sheet manufactured by the ethoxylation of cellulose under controlled conditions, to which may be added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in Parts 170 through 189 of this chapter, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances permitted to be used in water-insoluble hydroxyethyl cellulose film by prior sanction or approval and under conditions specified in such sanctions or approval, and substances listed in Part 181, Subpart B of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of water-insoluble hydroxyethyl cellulose film.

(4) Substances identified in and used in compliance with § 177.1200(c).

(c) Any substance employed in the production of the water-insoluble hydroxyethyl cellulose film described in this section that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

§ 177.1420 Isobutylene polymers.

Isobutylene polymers may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, isobutylene polymers are those produced as follows:

(1) Polyisobutylene produced by the homopolymerization of isobutylene such that the finished polymers have a molecular weight of 750,000 (Flory) or higher.

(2) Isobutylene-isoprene copolymers produced by the copolymerization of isobutylene with not more than 3 molar percent of isoprene such that the finished polymers have a molecular weight of 300,000 (Flory) or higher.

(3) Chlorinated isobutylene-isoprene copolymers produced when isobutylene-isoprene copolymers (molecular weight 300,000 (Flory) or higher) are modified by chlorination with not more than 1.3 weight-percent of chlorine.

(b) The polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of the polymers. The optional adjuvant substances required in the production of the polymers may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and aluminum chloride.

(c) The provisions of this section are not applicable to polyisobutylene used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1430 Isobutylene-butene copolymers.

Isobutylene-butene copolymers identified in this section may be safely used as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, isobutylene-butene copolymers consist of basic copolymers produced by the copolymerization of isobutylene with mixtures of *n*-butenes such that the finished basic copolymers contain not less than 45 weight percent of polymer units derived from isobutylene and meet the following specifications:

(1) Average molecular weight is in the range 300–5,000 as determined by

ASTM method D2503-82, "Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Viscosity is in the range 40-20,000 seconds Saybolt at 200° F as determined by ASTM mehtod D445-74, "Test for Kinematic Viscosity of Transparent and Opaque Liquids" (Revised 1974), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philladelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Maximum bromine value is 40 as determined by ASTM method D1492-78, "Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(b) The isobutylene-butene basic copolymers are limited to use:

(1) As a release agent in petroleum wax complying with § 178.3710 of this chapter.

(2) As a plasticizer in polyethylene complying with § 177.1520 and in polystyrene complying with § 177.1640.

(3) As a component of nonfood articles complying with §§ 175.300, 176.170, 176.210, 177.2260(d)(2), 177.2800, 178.3570 (provided that addition to food does not exceed 10 parts per million), or § 176.180 of this chapter.

(c) The provisions of this section are not applicable to isobutylene-butene copolymers used as provided under § 175.105 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11842, Mar. 19, 1982; 49 FR 10109, Mar. 19, 1984]

§ 177.1440 4,4′-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.

4,4′-Isopropylidenediphenol-epichlorohydrin resins having a minimum molecular weight of 10,000 may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) 4,4′-Isopropylidenediphenol-epichlorohydrin resins consist of basic resins produced by the condensation of equimolar amounts of 4,4′-isopropylidenediphenol and epichlorohydrin terminated with phenol, to which may have been added certain optional adjuvant substances required in the production of the resins.

(b) The optional adjuvant substances required in the production of the resins may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
Butyl alcohol	Not to exceed 300 p.p.m. as residual solvent in finished resin.
Ethyl alcohol	
Toluene	Not to exceed 1,000 p.p.m. as residual solvent in finished resin.

(c) 4,4′-Isopropylidenediphenol-epichlorohydrin resins shall meet the following nonvolatile extractives limitations:

(1) Maximum extractable nonvolatile fraction of 2 parts per million when extracted with distilled water at 70° C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(2) Maximum extractable nonvolatile fraction of 3 parts per million when extracted with *n*-heptane at 70° C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(3) Maximum extractable nonvolatile fraction of 6 parts per million when extracted with 10 percent (by volume) ethyl alcohol in distilled water at 70° C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(d) The provisions of this section are not applicable to 4,4′-isopropylidenediphenol-epichlorohydrin resins listed in other sections of Subchapter B of this chapter.

§ 177.1460 Melamine-formaldehyde resins in molded articles.

Melamine-formaldehyde resins may be safely used as the food-contact surface of molded articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) For the purpose of this section, melamine-formaldehyde resins are those produced when 1 mole of melamine is made to react with not more than 3 moles of formaldehyde in water solution.

(b) The resins may be mixed with refined woodpulp and the mixture may contain other optional adjuvant substances which may include the following:

List of substances	Limitations
Dioctyl phthalatemine	For use as lubricant.
Hexamethylenetetramine	For use only as polymerization reaction control agent.
Phthalic acid anhydride	Do.
Pigments and colorants identified in § 175.300(b)(3)(xxvi) of this chapter.	
Zinc stearate	For use as lubricant.

(c) The molded melamine-formaldehyde articles in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature as determined from Tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

§ 177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.

Nitrile rubber modified acrylonitrile-methyl acrylate copolymers identified in this section may be safely used as components of articles intended for food-contact use under conditions of use D, E, F, or G described in table 2 of § 176.170(c) of this chapter, subject to the provisions of this section.

(a) For the purpose of this section, nitrile rubber modified acrylonitrile-methyl acrylate copolymers consist of basic copolymers produced by the graft copolymerization of 73-77 parts by weight of acrylonitrile and 23-27 parts by weight of methyl acrylate in the presence of 8-10 parts by weight of butadiene-acrylonitrile copolymers containing approximately 70 percent by weight of polymer units derived from butadiene.

(b) The nitrile rubber modified acrylonitrile-methyl acrylate basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Nitrogen content is in the range 16.5-19 percent as determined by Kjeldahl analysis.

(ii) Intrinsic viscosity in acetonitrile at 25° C is not less than 0.29 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(iii) Residual acrylonitrile monomer content is not more than 11 parts per million as determined by gas chromatography.

(iv) Acetonitrile-soluble fraction after refluxing the base polymer in acetonitrile for 1 hour is not greater than 95 percent by weight of the basic copolymers.

(2) *Extractives limitations.* The following extractive limitations are determined by an infrared spectrophotometric method titled, "Infrared Spectrophotometric Determination of Polymer Extracted from Borex® 210 Resin Pellets," which is incorporated by ref-

erence. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408, and are applicable to the basic copolymers in the form of particles of a size that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10:

(i) Extracted copolymer not to exceed 2.0 parts per million in aqueous extract obtained when a 100-gram sample of the basic copolymers is extracted with 250 milliliters of demineralized (deionized) water at reflux temperature for 2 hours.

(ii) Extracted copolymer not to exceed 0.5 part per million in *n*-heptane extract obtained when a 100-gram sample of the basic copolymers is extracted with 250 milliliters of reagent grade *n*-heptane at reflux temperature for 2 hours.

(c) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(d) Acrylonitrile copolymers identified in this section are not authorized to be used to fabricate beverage containers.

(Secs. 201(s), 402, 52 Stat. 1046-1047 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 48544, Sept. 23, 1977; 47 FR 11843, Mar. 19, 1982; 47 FR 16775, Apr. 20, 1982; 49 FR 10109, Mar. 19, 1984]

§ 177.1500 Nylon resins.

The nylon resins listed in paragraph (a) of this section may be safely used to produce articles intended for use in processing, handling, and packaging food, subject to the provisions of this section:

(a) The nylon resins are manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (c) of this section.

(1) Nylon 66 resins are manufactured by the condensation of hexamethylene-diamine and adipic acid.

(2) Nylon 610 resins are manufactured by the condensation of hexamethylene-diamine and sebacic acid.

(3) Nylon 66/610 resins are manufactured by the condensation of equal-weight mixtures of nylon 66 salts and nylon 610 salts.

(4) Nylon 6/66 resins are manufactured by the condensation and polymerization of mixtures of nylon 66 salts and *epsilon*-caprolactam under such conditions that the *epsilon*-caprolactam monomer content does not exceed 0.7 percent by weight of the finished nylon 6/66 resins.

(5) Nylon 11 resins are manufactured by the condensation of 11-aminoundecanoic acid.

(6) Nylon 6 resins are manufactured by the polymerization of *epsilon*-caprolactam.

(7) Nylon 66T resins are manufactured by the condensation of hexamethyl-enediamine, adipic acid, and terephthalic acid such that composition in terms of ingredients is 43.1±0.2 weight percent hexamethyl-enediamine, 35.3±1.2 weight percent adipic acid, and 21.6±1.2 weight percent terephthalic acid.

(8) Nylon 612 resins are manufactured by the condensation of hexamethylenediamine and dodecanedioic acid.

(9) Nylon 12 resins are manufactured by the condensation of *omega*-laurolactam.

(10)(i) Impact modified Nylon MXD-6 resins (CAS Reg. No. 59655-05-9) manufactured by the condensation of adipic acid, 1,3-benzenedimethanamine, and *alpha*-(3-aminopropyl)-*omega*-(3-amino-propoxy)poly- oxyethylene under such conditions that the *alpha*-(3-amino-propyl)-*omega*-(3-aminopropoxy) polyoxyethylene monomer content does not exceed 7 percent by weight of the finished resin.

(ii) Nylon MXD-6 resins (CAS Reg. No. 25718-70-1) manufactured by the condensation of adipic acid and 1,3-benzenedimethanamine.

(11) Nylon 12T resins are manufactured by the condensation of *omega*-laurolactam (CAS Reg. No. 0947-04-6), isophthalic acid (CAS Reg. No. 0121-

91-5), and bis(4-amino-3-methylcyclohexyl)methane (CAS Reg. No. 6864-37-5) such that the composition in terms of ingredients is 34.4 ± 1.5 weight percent *omega*-laurolactam, 26.8 ± 0.4 weight percent isophthalic acid, and 38.8 ± 0.5 weight percent bis(4-amino-3-methylcyclohexyl)-methane.

(b) Specifications:

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2*N* HCl	Maximum extractable fraction as selected solvents (expressed in percent by weight of resin)			
				Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
1. Nylon 66 resins	1.14±.015	475–495	Dissolves in 1 h	1.5	1.5	0.2	0.2
2. Nylon 610 resins	1.09±.015	405–425	Insoluble after 1 h	1.0	2.0	1.0	1.0
3. Nylon 66/610 resins	1.10±.015	375–395	Dissolves in 1 h	1.5	2.0	1.0	1.0
4. Nylon 6/66 resins	1.13±.015	440–460	do	2.0	2.0	1.5	1.5
5.1 Nylon 11 resins for use in articles intended for 1-time use or repeated use in contact with food.	1.04±.015	355–375	Insoluble after 1 h	.30	.35	.25	.3
5.2 Nylon 11 resins for use only: a. In articles intended for repeated use in contact with food. b. In side-seam cements for articles intended for 1-time use in contact with food and which are in compliance with § 175.300 of this chapter.	1.04±.015	355–375	do	.35	1.60	.35	.40
6.1 Nylon 6 resins	1.15±.015	392–446	Dissolves in 1 h	1.0	2.0	1.0	1.0
6.2 Nylon 6 resins for use only in food-contact films having an average thickness not to exceed 0.001 in.	1.15±.015	392-446	do	1.5	2.0	1.0	1.0
7. Nylon 66T resins for use only in food-contact films having an average thickness not to exceed 0.001 in.	1.16±.015	482-516	Insoluble after 1 h	1.0	1.0	.25	.25
8. Nylon 612 resins for use only in articles intended for repeated use in contact with food at temperatures not to exceed 212° F..	1.06±.015	406–420	do	.50	1.50	.50	.50
9. Nylon 12 resins for use only in food-contact films having an average thickness not to exceed 0.0016 inch intended for use in contact with nonalcoholic food under the conditions of use A (sterilization not to exceed 30 minutes at a temperature not to exceed 250°F), and B through H of Table 2 of § 176.170(c) of this chapter, except as provided in § 177.1390(d).	1.01±.015	335–355	do	1.0	2.0	1.50	1.50
10.1 Nylon MXD–6 and impact modified Nylon MXD–6 film having an average thickness not to exceed 40 microns (0.0016 inch) for use in processing, handling, and packaging of food of types V and IX listed in table 1 of § 176.170(c) of this chapter under conditions of use C, D, E, F, G, and H in table 2 of § 176.170(C) of this chapter.	1.21±0.02	437–491	Dissolves in 1h	2.0	2.5	1.0	1.0

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2*N* HCl	Maximum extractable fraction as selected solvents (expressed in percent by weight of resin)			
				Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
10.2 Impact modified Nylon MXD-6 resins for use as polymer use as polymer modifiers in Nylon 6 resin films complying with paragraph (a)(6) of this section, at levels not to exceed 13 percent by weight of films whose average thickness will not exceed 15 microns (0.6 mils). The finished film is used for packaging, transporting, or holding food, excluding beverages containing more than 8 percent alcohol (by volume) at temperatures not to exceed 49 °C (120 °F) (conditions of use E, F, and G in table 2 of § 176.170(c) of this chapter).	1.21±0.02	437–491	do	2.0	2.5	1.0	1.0
11. Nylon 12T resins for use in contact with all types of food except those containing more than 8 percent alcohol.	1.06±0.015	290–310	Insoluble after 1 hour	0.1		0.5	0.5

(c) *Analytical methods*—(1) *Specific gravity.* Specific gravity shall be determined by weighing a 1-gram to 5-gram sample first in air and then in freshly boiled distilled water at 23° C±2° C.

(2) *Melting point.* The melting point shall be determined as follows: Use a hot-stage apparatus. The use of crossed nicol prisms with a microscope hot stage and reading of the thermometer when the birefringence disappears increases the accuracy. If the crossed nicol apparatus is not available, use the lowest temperature at which the sample becomes transparent or the sharp edges or corners of the sample become rounded as the melting point. In case of doubt as to the onset of melting, the sample is prodded with a sharp instrument. If it sticks to the heating block, it is considered to have melted. If the melting point is low, dry the sample in an oven at 85° C for 24 hours in a nitrogen atmosphere then repeat the test.

(3) *Solubility in boiling 4.2N HCl.* The test shall be run on a sample approximately the size of a ⅛-inch cube in at least 25 milliliters of 4.2 normal hydrochloric acid.

(4) *Maximum extractable fraction in selected solvents.* The procedure for determining the maximum extractable fraction of the nylon resins in selected solvents is as follows:

(i) Film should be cut with ordinary scissors into pieces of a convenient size such as ¼-inch squares, for the extraction tests described in this section. The granules of nylon molding powders are in the proper form for the extraction tests. Samples of fabricated articles such as pipe, fittings, and other similar articles must be cut to approximately the size of the molding powder. This can be done conveniently by using a small-scale commercial plastics granulator and cutting the sample through a screen having ¼-inch mesh. Fine particles should be separated from the cut resin by screening through a 20-mesh screen. The material retained on the screen is suitable for the extraction tests.

(ii) The organic solvents must be of American Chemical Society analytical reagent grade; distilled water is used. Approximately 30 grams of the prepared sample is weighed to the nearest milligram. The weighed resin is transferred to a 500-milliliter round-bottom flask equipped with a reflux condenser. Approximately 300-milliliters of solvent is added to the flask and the contents refluxed gently for 8 hours with a heating mantle. The solvent is then filtered off immediately while still hot, using a Buchner funnel approximately 5 inches in diameter, a suction flask, and a hardened filter paper (Whatman No. 50 or equivalent). The paper is wet with the solvent and a slight suction applied just before starting the filtration. The resin is washed twice with approximately 100-milliliter portions of solvent and the combined filtrate and washings are reduced to approximately 25 milliliters by evaporation at reduced pressure (50 millimeters to 100 millimeters of mercury, absolute), heating as necessary. The contents of the flask are transferred to an evaporation dish (which has been held in a vacuum desiccator over anhydrous calcium sulfate until constant weight has been attained) and carefully evaporated to dryness. The weight of the solid residue is determined by difference after holding in a vacuum desiccator over anhydrous calcium sulfate until constant weight has been attained. The percent of solids extracted is calculated by dividing the weight of the solid residue by the weight of the sample and multiplying by 100.

[42 FR 14572, Mar. 15, 1977, as amended at 45 FR 2844, Jan. 15, 1980; 48 FR 30361, July 1, 1983; 48 FR 33478, July 22, 1983; 48 FR 36099, Aug. 9, 1983; 51 FR 33250, Sept. 19, 1986]

§ 177.1520 Olefin polymers.

The olefin polymers listed in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, olefin polymers are basic polymers manufactured as described in this paragraph, so as to meet the specifications prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(1) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

(2) Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(3) Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of:

(i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that:

(*a*) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 or ethylene and octene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene;

(*b*) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4-methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;

(*c*) Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4-trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene;

(*d*) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, hexene-1, and either propylene or butene-1, shall contain not less than 85 weight percent polymer units derived from ethylene.

(ii) 4-Methylpentene-1 and 1-alkenes having 6 to 10 carbon atoms. Such olefin basic copolymers shall contain not less than 95 molar percent of polymer units derived from 4-methylpentene-1; or

(iii) Ethylene and propylene that may contain as modifiers not more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

5-Ethylidine-2-norbornene.
5-Methylene-2-norbornene.

(iv) Ethylene and propylene that may contain as a modifier not more than 4.5 weight percent of total polymer units derived by copolymerization with 1,4-hexadiene.

(v) Ethylene and butene-1 copolymers (CAS Reg. No. 25087-34-7) that shall contain not less than 80 weight percent of polymer units derived from ethylene.

(4) Poly(methylpentene) consists of basic polymers manufactured by the catalytic polymerization of 4-methylpentene-1.

(b) The basic olefin polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic olefin polymers. The optional adjuvant substances required in the production of the basic olefin polymers or finished food-contact articles may include substances permitted for such use by applicable regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food and food packaging, substances used in accordance with a prior sanction or approval, and the following:

Substance	Limitations
2,5-Dimethyl-2,5-di(*tert*-butylperoxy)hexane (CAS Reg. No. 78-63-7).	For use as an initiator in the production of polypropylene complying with § 177.1520 (a)(1), provided that the maximum concentration of *tert*-butyl alcohol detected in the polymer does not exceed 25 parts per million, as determined by a method titled "Determination of *tert*-Butyl Alcohol in Polypropylene," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-300), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.
7-(2*H*-Naphtho[1, 2-*d*]triazol-2-yl)-3-phenyl-coumarin [Chemical Abstracts Service Registry No. 3333-62-8] having a melting point of 250° to 251° C and a nitrogen content of 10.7 to 11.2 percent.	For use as an optical brightener only at levels such that the product of concentration of the optical brightener (expressed in parts per million by weight of the olefin polymer) multiplied by the thickness of the olefin polymer (expressed in thousandths of an inch and limited to no more than 0.400 inch) shall not exceed 500; provided that the level of the brightener shall not exceed 20 parts per million by weight of the olefin polymer, and further that the olefin polymers shall comply with specifications for items 1.1, 2.1, 3.1, 3.3, and 4 of paragraph (c) of this section and are used under the conditions described in § 176.170(c) of this chapter, Table 2 under conditions of use E, F, and G.
Trimethylpyridine and dimethylpyridine mixture having percent by weight composition as follows: 2,4,6-trimethylpyridine (CAS Reg. No. 108-75-8), not less than 60 percent; 2,3,6-trimethylpyridine (CAS Reg. No. 1462-84-6), not more than 27 percent; 3,5-dimethylpyridine (CAS Reg. No. 591-22-0), not more than 12 percent; and other dimethylpyridines, not more than 6 percent.	For use only as an adjuvant substance in the production of propylene homopolymers complying with items 1.1, 1.2, and 1.3, and propylene copolymers complying with items 3.1, and 3.2 of paragraph (c) of this section provided that the adjuvant is used at a level not to exceed 20 parts per million by weight of the olefin polymers.
Vinylidene fluoride-hexafluoropropene copolymer (CAS Reg. No. 9011-17-0) having a fluorine content of 65 to 66 percent and a Mooney viscosity of 28 to 38, as determined by a method entitled "Mooney Viscosity," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	For use only as an extrusion aid in the production of extruded olefin polymers at levels not to exceed 0.1 percent by weight of the polymer. The finished polymers may be used only in contact with nonalcoholic foods under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use B through H.

(c) *Specifications:*

Olefin polymers	Density	Melting point (MP) or softening point (SP) (*Degrees Centigrade*)	Maximum extractable fraction (expressed as percent by weight of polymer) in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
1.1 Polypropylene	0.880-0.913	MP: 160°-180° C	6.4 pct at reflux temperature	9.8 pct at 25° C.

Olefin polymers	Density	Melting point (MP) or softening point (SP) (*Degrees Centrigrade*)	Maximum extractable fraction (expressed as percent by weight of polymer) in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
1.2 Polypropylene, noncrystalline; for use only to plasticize polyethylene described under items 2.1 and 2.2 of this table, provided that such plasticized polymers meet the maximum extractable fraction and maximum soluble fraction specifications prescribed for such basic polyethylene.	0.80–0.88			
1.3 Polypropylene, noncrystalline, for use only: To plasticize polypropylene described by item 1.1 of this table, provided that such plasticized polymers meet the maximum extractable fraction and maximum soluble fraction specifications prescribed for such basic polypropylene, and further provided that such plasticized polypropylene contacts food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types I, II, IV-B, VI-B, VII-B, and VIII; and for use at levels not to exceed 50 pct by weight of any mixture employed as a food-contact coating provided such coatings contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types I, II, IV-B, VI-B, VII-B, and VIII.	0.80–0.88	SP:115°–138° C		
2.1 Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking.	0.85–1.00		5.5 pct at 50° C	11.3 pct at 25° C.
2.2 Polyethylene for use in articles used for packing or holding food during cooking.	0.85–1.00		2.6 pct at 50° C	Do.
2.3 Polyethylene for use only as component of food-contact coatings at levels up to and including 50 percent by weight of any mixture employed as a food-contact coating.	0.85–1.00		53 pct at 50° C	75 pct at 25° C.
3.1 Olefin copolymers described in par. (a)(3)(i) of this section for use in articles that contact food except for articles used for packing or holding food during cooking.	0.85–1.00		5.5 pct at 50° C	30 pct at 25° C.
3.2 Olefin copolymers described in paragraph (a)(3)(i) of this section for use in articles used for packing or holding food during cooking; except that olefin copolymers containing 89–95 percent ethylene with the remainder being 4-methyl-pentene-1 contacting food Types III, IVA, V, VIIA, and IX identified in § 176.170(c) of this chapter, Table 1, shall not exceed 0.051 mm (0.002 in.) in thickness when used under conditions of use A and shall not exceed 0.102 mm (0.004 in.) in thickness when used under conditions of use B, C, D, E, and H described in § 176.170(c) of this chapter, Table 2.	0.85–1.00		2.6 percent at 50° C	Do.
3.3 Olefin copolymers described in par. (a)(3)(ii) of this section.	0.82–0.85	MP: 235°– 250° C	6.6 pct at reflux temperature.	7.5 pct at 25° C.

Olefin polymers	Density	Melting point (MP) or softening point (SP) (*Degrees Centrigrade*)	Maximum extractable fraction (expressed as percent by weight of polymer) in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
3.4 Olefin copolymers, primarily noncrystalline, described in par. (a)(3) (iii) of this section provided that such olefin polymers have a minimum viscosity average molecular weight of 120,000 as determined by the method described in par. (d)(5) of this section and a minimum Mooney viscosity of 35 as determined by the method described in par. (d)(6) of this section, and further provided that such olefin copolymers contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types I, II, III, IV-B, VI, VII, VIII, and IX.	0.85–0.90			
3.5 Olefin copolymers, primarily noncrystalline, described in paragraph (a)(3)(iv) of this section, provided that such olefin polymers have a minimum viscosity average molecular weight of 95,800 as determined by the method described in paragraph (d)(5) of this section, and further provided that such olefin polymers are used only in blends with olefin polymers described under items 1.1, 2.1, and 2.2 of this table at a maximum level of 25 pct by weight, and provided that such olefin copolymers contact food only of the types identified in § 176.170 (c) of this chapter, Table 1, under Types I, II, IV-B, VI, VII-B, and VIII at temperatures not exceeding 190° F.	0.85–0.90			
3.6 Olefin copolymers described in paragraph (a)(3)(v) of this section for use in blends with olefin polymer resins have a melt flow index no greater than 5 grams/10 minutes as determined by the method described in paragraph (d)(7) of this section and the thickness of the finished blends shall not exceed 0.1 millimeter (0.004 inch). The ethylene/butene-1 copolymer may be used subject to the following conditions: (1) For use at a level not to exceed 20 weight percent in polypropylene as described under item 1.1 of this table. (2) For use at a level not to exceed 40 weight percent in polyethylene as described under items 2.1 and 2.2 of this table. (3) For use at a level not to exceed 40 weight percent in olefin copolymers as described under items 3.1 and 3.2 of this table.	Not less than 0.88			
4. Poly(methylpentene)	0.82–0.85	MP: 235°–250° C.	6.6 pct at reflux temperature.	7.5 pct at 25° C.

(d) The analytical methods for determining whether olefin polymers conform to the specifications prescribed in this section are as follows, and are applicable to the basic polymer in film form not exceeding 4 mils in thickness. The film to be tested shall be cut into approximately 1-inch squares by any convenient method that avoids contamination by dust, dirt, or grease (NOTE: Do not touch samples with bare fingers—use forceps to hold or transfer samples).

(1) *Density.* Density shall be determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Melting point or softening point*—(i) *Melting point.* The melting point shall be determined by ASTM method D2117-82, "Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(ii) *Softening point.* The softening point shall be determined by ASTM method E28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(3) *Maximum extractable fraction in n-hexane*—(i) *Olefin copolymers described in paragraph (a)(3)(ii) of this section, polypropylene, and poly(methylpentene).* A sample is refluxed in the solvent for 2 hours and filtered at the boiling point. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction.

(*a*) *Apparatus.* (*1*) Erlenmeyer flasks, 250-milliliter, with ground joint.

(*2*) Condensers, Allihn, 400-millimeter jacket, with ground joint.

(*3*) Funnels, ribbed 75-millimeter diameter, stem cut to 40 millimeters.

(*4*) Funnels, Bu 4chner type, with coarse-porosity fritted disc, 60-millimeter diameter.

(*5*) Bell jar for vacuum filtration into beaker.

(*b*) *Reagent.* *n*-Hexane, commercial grade, specific gravity 0.663-0.667 (20° C/20° C), boiling range 66° C-69° C, or equivalent.

(*c*) *Procedure.* Weigh 1 gram of sample accurately and place in a 250-milliliter Erlenmeyer flask containing two or three boiling stones. Add 100 milliliters of solvent, attach the flask to the condenser (use no grease), and reflux the mixture for 2 hours. Remove the flask from the heat, disconnect the condenser, and filter rapidly, while still hot, through a small wad of glass wool packed in a short-stem funnel into a tared 150-millimeter beaker. Rinse the flask and filter with two 10-milliliter portions of the hot solvent, and add the rinsings to the filtrate. Evaporate the filtrate on a stream bath with the aid of a stream of nitrogen. Dry the residue in a vacuum oven at 110° C for 2 hours, cool in a desiccator, and weigh to the nearest 0.0001 gram. Determine the blank on 120 milliliters of solvent evaporated in a tared 150-milliliter beaker. Correct the sample residue for this blank if significant. Calculation:

Grams of residue/Grams of sample $\times 100 =$ Percent extractable with *n*-hexane.

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene.* A sample is extracted at 50° C in the solvent for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction.

(*a*) *Extraction apparatus.* Two-liter, straight-walled, Pyrex (or equivalent) resin kettles, fitted with three-hole ground-glass covers are most convenient for this purpose. The cover is fitted with a thermometer, a gas-tight stirrer driven by an air motor or explosion-proof electric motor, and a reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape, which is controlled by a variable-voltage transformer.

(*b*) *Evaporating apparatus.* Rapid evaporation of large volumes of solvent requires special precautions to prevent contamination by dust. This is facilitated by a special "gas" cover consisting of an inverted flat Pyrex crystallizing dish of an appropriate size (190 millimeters x 100 millimeters) to fit a 1-liter beaker. Through the center of the dish are sealed an inlet tube for preheated, oxygen-free nitrogen, and an outlet tube located 1 inch off center. Nitrogen is fed from the supply source through a coil of ¼-inch stainless steel tubing immersed in the same steam bath used to supply heat for solvent evaporation. All connections are made with flexible tetrafluoroethylene tubing.

(*c*) *Reagents*—(*1*) *n-Hexane*. Spectrograde *n*-hexane.

(*2*) *Nitrogen*. High-purity dry nitrogen containing less than 10 parts per million of oxygen.

(*d*) *Procedure*. Transfer 2.5 grams (accurately weighed to nearest 0.001 gram) of the polymer to the resin kettle. Add 1 liter of solvent and clamp top in position. Start water flowing through jacket of the reflux condenser and apply air pressure to the stirring motor to produce vigorous agitation. Turn on heating jacket with transformer set at a predetermined voltage to bring the temperature of the contents to 50° C within 20-25 minutes. As the thermometer reading approaches 45° C-47° C, reduce the voltage to the predetermined setting that will just maintain the temperature at 50° C. Do not overshoot the prescribed temperature. Should this occur discard the test and start afresh. Exactly 2 hours after the solvent temperature has reached 50° C, disconnect the heater, remove the resin kettle from the heating jacket, and decant the solvent, while still warm, through a coarse filter paper placed on top of a fritted-glass funnel, collecting the filtrate in a tared, glass-stoppered Erlenmeyer flask of 1-liter capacity. Determine the weight of the filtrate recovered to the nearest gram. Recovery should be at least 90 percent of the original solvent. Losses due to evaporation during heating and filtering have been found not to exceed 10 percent. Transfer about half of the solvent filtrate to a 1-liter beaker placed on an opening in the steam bath and immediately cover with the special "gas" cover, the inlet tube of which has been attached with flexible tetrafluoroethylene tubing to a source of high-purity nitrogen in series with a stainless steel heating coil immersed directly in the body of the steam bath. Maintain a positive flow of warm nitrogen gas throughout the evaporation of the solvent, adding the remainder of the filtrate from the Erlenmeyer flask as the evaporation proceeds. When the volume of the solvent has been reduced to about 50 milliliters, transfer the concentrated liquid to a previously tared weighing dish of suitable size. Wash the beaker twice with 20-30 milliliter portions of warm solvent, adding the washings to the weighing dish while continuing to evaporate the remainder of the solvent under the gas cover with its flow of warm nitrogen directed toward the center of the dish. In the event that an insoluble residue that cannot be removed with warm solvent remains in the beaker, it may be necessary to heat with a small amount of a higher boiling solvent such as benzene or toluene, transferring these washings to the weighing dish before final evaporation to dryness. Transfer the weighing dish with its residue to a vacuum desiccator, and allow it to remain overnight (at least 12 hours), after which the net weight of the dry residue is determined to the nearest 0.0001 gram. Correct the result for any solvent blank equivalent to the nonvolatile matter determined to be contained in the amount of solvents used in the test.

(4) *Maximum soluble fraction in xylene*—(i) *Olefin copolymers described in paragraph* (*a*)(*3*)(*ii*) *of this section, polypropylene, and poly*(*methylpentene*). A sample is dissolved completely in xylene by heating and stirring in a bottle with little free space. The solution is allowed to cool without stirring, whereupon the insoluble portion precipitates and is filtered off; the total solids content of the filtrate is then determined as a measure of the soluble fraction.

(*a*) *Apparatus*. (*1*) Pyrex (or equivalent) reagent bottle, 125-milliliter, glass-stoppered.

(*2*) Heating mantle of size for 150-milliliter beaker (or suitable aluminum block to fit the 125-milliter bottle described in paragraph (d)(4)(i)(*a*)(*1*) of this section.

(*3*) Magnetic stirrer for use under the heating mantle (combination magnetic stirrer and hotplate may be used if aluminum block is used in place of heating mantle).

(*4*) Variable-voltage transformer, 7.5 amperes.

(*5*) Tetrafluoroethylene-resin-coated stirring bar, 1-inch long.

(*6*) Constant temperature water bath maintained at 25° C±0.5° C.

(*7*) *Aluminum* dishes, 18 millimeters x 60 millimeters, disposable.

(*8*) Funnel, Bu 4chner type, with coarse-porosity fritted disc, 30–60 millimeter diameter.

(*b*) *Reagent.* Xylene with antioxidant. Dissolve 0.020 gram of phenyl-β-naphthylamine in 1 liter of industrial grade xylene having specific gravity 0.856–0.867 (20° C/20° C) and boiling range 123° C–160° C.

(*c*) *Procedure.* Weigh 1 to 2 grams of sample to the nearest 0.001 gram and place in a 125-milliliter Pyrex reagent bottle containing a 1-inch long tetrafluoroethylene-resin-coated stirring bar. Add 100 milliliters of solvent, set the stopper in lightly, and place the bottle in the heating mantle or aluminum block maintained at a temperature of 120° C, and stir with a magnetic stirrer until the sample is completely dissolved. Remove the bottle from the heat and allow it to cool 1 hour in the air, without stirring. Then place the bottle in a water bath maintained at 25° C±0.5° C, and allow to stand 1 hour without stirring. Next, remove the bottle from the water bath, shake, and pour part of the contents into the coarse-porosity fritted-glass funnel. Apply suction, and draw 30–40 milliliters of filtrate through, adding more slurry to the funnel, and catching the filtrate in a large test tube. (If the slurry is hard to filter, add 10 grams of diatomaceous earth filter aid to the bottle and shake vigorously just prior to the filtration.) Pipet a suitable aliquot (preferably 20 milliliters) of the filtrate into a tared aluminum disposable dish. Place the dish on a steam bath covered with a fresh sheet of aluminum foil and invert a short-stemmed 4-inch funnel over the dish. Pass nitrogen (heated if desired) down through the funnel at a rate sufficient to just ripple the surface of the solvent. When the liquid has evaporated, place the dish in a vacuum oven at 140° C and less than 50 millimeters mercury pressure for 2 hours. Cool in a desiccator and weigh. (Note: If the residue value seems high, redry in the vacuum oven for one-half hour to ensure complete removal of all xylene solvent.) Calculation:

Grams of residue/Grams of sample × 100 milliliters/volume of aliquot in milliliters × 100=Percent soluble in xylene

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene.* A sample is extracted in xylene at reflux temperature for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of soluble fraction.

(*a*) *Apparatus—(1) Extraction apparatus.* Two-liter, straight-walled Pyrex (or equivalent) resin kettles, fitted with ground-glass covers, are most convenient for this purpose. The cover is equipped with a thermometer and an efficient reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape which is controlled by a variable-voltage transformer.

(*2*) *Constant temperature water bath.* It must be large enough to permit immersion of the extraction kettle and set to maintain 25° C±0.1° C.

(*3*) *Evaporating apparatus.* Gas cover consisting of a flat Pyrex crystallizing dish (190 millimeters x 100 millimeters) inverted to fit over a 1-liter beaker with 8-millimeter gas inlet tube sealed through center and an outlet tube 1 inch off center. The beaker with gas cover is inserted in an electric heating mantle equipped with a variable-voltage transformer. The outlet tube is attached to an efficient condenser mounted on a receiving flask for solvent recovery and having an outlet for connection to an aspirator pump. The heating mantle (with the beaker) is mounted on a magnetic stirring device. An infrared heat lamp is mounted vertically 3-4 inches above the gas cover to prevent condensation of the solvent inside the cover. Make all connections with flexible tetrafluoroethylene tubing.

(*b*) *Reagents—(1) Xylene.* American Chemical Society reagent grade that has been redistilled through a fractionating column to reduce the nonvolatile residue.

(*2*) *Nitrogen.* High-purity dry nitrogen containing less than 10^4 parts per million oxygen.

(*c*) *Procedure.* Transfer 5 grams ±0.001 gram of sample to the resin kettle, add 1,000 milliliters (840 grams) of xylene, and clamp top in position after inserting a piece of glass rod to prevent bumping during reflux. Start water flowing through the jacket of the reflux condenser and apply full voltage (115 volts) to the heating mantle. When the xylene starts to boil, reduce the voltage to a level just sufficient to maintain reflux. After refluxing for at least 2 hours, disconnect the power source to the mantle, remove the kettle, and allow to cool in air until the temperature of the contents drops to 50° C, after which the kettle may be rapidly cooled to 25° C-30° C by immersing in a cold water bath. Transfer the kettle to a constant temperature bath set to maintain 25° C ±0.1° C, and allow to equilibrate for a least 1 hour (may be left overnight if convenient). Break up any precipitated polymers that may have formed, and decant the xylene solution successively through a fast filter paper and then through a fritted-glass filter into a tared 1-liter Erlenmeyer flask, collecting only the first 450 milliliters—500 milliliters of filtrate (any attempt to collect more of the xylene solution usually results in clogging the filter and risking losses). Reweigh the Erlenmeyer flask and calculate the weight of the filtrate obtained to the nearest 0.1 gram. Transfer the filtrate, quantitatively, from the Erlenmeyer flask to the 1-liter beaker, insert the beaker in its heating mantle, add a glass-coated magnetic stirring bar, and mount the gas cover in place, connecting the inlet tube to the nitrogen source and the outlet to the condenser of the receiving flask. Start a flow of nitrogen (2 to 3 liters per minute) into the gas cover and connect an aspirator to the receiver using a free-flow rate equivalent to 6-7 liters of air per minute. With the infrared lamp on, adjust the voltage to the heating mantle to give a distillation rate of 12-13 milliliters per minute when the magnetic stirrer is revolving just fast enough to promote good boiling. When the volume of solvent in the beaker has been reduced to 30-50 milliliters, transfer the concentrated extractive to a suitable weighing dish that has been previously tared (dry). Rinse the beaker twice with 10-20 milliliter portions of fresh xylene, adding the rinsings to the weighing dish. Evaporate the remainder of the xylene on an electric hotplate set at low heat under the gas cover with a stream of nitrogen directed toward the center of the dish. Avoid any charring of the residue. Transfer the weighing dish to a vacuum desiccator at room temperature and allow to remain under reduced pressure for at least 12 hours (overnight), after which determine the net weight of the residue to the nearest 0.0001 gram. Correct the result for nonvolatile solvent blank obtained by evaporating the equivalent amount of xylene under identical conditions. Calculate the weight of residue originally present in the total weight of solvent (840 grams), using the appropriate factor based on the weight of filtrate evaporated.

(5) *Viscosity average molecular weight olefin copolymers described in paragraphs* (*a*) (*3*) (*iii*) *and* (*iv*) *of this section.* The viscosity average molecular weight shall be determined from the kinematic viscosity (using ASTM method D445-74, "Test for Kinematic Viscosity of Transparent and Opaque Liquids" (Revised 1974), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) of solutions of the copolymers in solvents and at temperatures as follows:

(i) Olefin polymers described in paragraph (a)(3)(iii) of this section in decahydronaphthalene at 135° C.

(ii) Olefin polymers described in paragraph (a)(3)(iv) of this section in tetrachloroethylene at 30° C.

(6) *Mooney viscosity—olefin copolymers described in paragraph* (*a*)(*3*)(*iii*) *of this section.* Mooney viscosity is determined by ASTM method D1646-81, "Standard Test Method for Rubber—Viscosity and Vulcanization Characteristics (Mooney Viscometer)," which is incorporated by reference (the avail-

ability of this incorporation by reference is given in paragraph (d)(1) of this section), using the large rotor at a temperature of 100° C, except that a temperature of 127° C shall be used for those copolymers whose Mooney viscosity cannot be determined at 100° C. The apparatus containing the sample is warmed for 1 minute, run for 8 minutes, and viscosity measurements are then made.

(7) *Melt flow index.* The melt flow index of the olefin polymers described in paragraph (a)(3)(v) of this section shall be determined by ASTM method D-1238-82, condition E, Procedure A, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer, " which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(e) Olefin copolymers described in paragraph (a)(3) (i) of this section and polyethylene, alone or in combination, may be subjected to irradiation bombardment from a source not to exceed 2.3 million volts intensity to cause molecular crosslinking of the polymers to impart desired properties, such as increased strength and increased ability to shrink when exposed to heat.

(f) The olefin polymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178, and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(g) The provisions of this section are not applicable to olefin polymers identified in § 175.105(c) (5) of this chapter and used in food-packaging adhesives complying with § 175.105 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 44 FR 59506, Oct. 16, 1979; 44 FR 74817, Dec. 18, 1979; 46 FR 16676, Mar. 13, 1981; 47 FR 11843, Mar. 19, 1982; 48 FR 26312, June 7, 1983; 49 FR 10109, Mar. 19, 1984; 50 FR 21833, May 29, 1985; 50 FR 31350, Aug. 2, 1985; 51 FR 43191, Dec. 1, 1986; 51 FR 45315, Dec. 18, 1986]

§ 177.1550 Perfluorocarbon resins.

Perfluorocarbon resins identified in this section may be safely used as articles or components of articles intended to contact food, subject to the provisions of this section:

(a) *Identity.* For the purpose of this section, perfluorocarbon resins are those produced by: (1) The homopolymerization and/or copolymerization of hexafluoropropylene and tetrafluoroethylene, and (2) the copolymerization of perfluoropropylvinylether and tetrafluoroethylene (CAS Reg. No. 26655-00-5). The resins shall meet the extractives limitations in paragraph (d) of this section.

(b) *Optional components.* The perfluorocarbon resins identified in paragraph (a) of this section as well as articles or coating made from these resins may include the following optional components except that the resin identified in paragraph (a)(2) of this section may not be used with the optional component, lithium polysilicate, mentioned in paragraph (b)(4) of this section.

(1) Substances generally recognized as safe (GRAS) in food or food packaging subject to any limitations cited on their use.

(2) Substances used in accordance with a prior sanction or approval, subject to any limitations cited in the prior sanction or approval.

(3) Substances authorized under applicable regulations in this part and in parts 175 and 178 of this chapter and subject to any limitations prescribed therein.

(4) The following substances, subject to any limitations prescribed:

List of substances	Limitations
Lithium polysilicate containing not more than 20 weight percent silica, not more than 2.1 percent lithium oxide and having a maximum mole ratio of SiO_2/Li_2O of 8.5 to 1.	For use only as a component of repeated-use coatings not exceeding 0.030 millimeter (0.0012 inch) in thickness where the coatings are thermally cured at minimum sintering temperatures of 371° C (700° F). Lithium extractives shall not exceed 1.55 milligrams per square decimeter (0.1 milligram per square inch) of coating surface when tested in accordance with paragraph (e)(2) of this section.
Naphthalene sulfonic acid formaldehyde condensate, sodium [illegible]	For use only: 1. As a component of repeated-use coatings, based on the perfluorocarbon resin identified in paragraph (a)(1) of this section, not to exceed 0.030 millimeter (0.0012 inch) in thickness, and at a level not to exceed 0.4 weight percent of the coating. 2. As a component of repeated-use coatings, based on the perfluorocarbon resin identified in paragraph (a)(2) of this section, not to exceed 0.10 millimeter (0.004 inch) in thickness, and at a level not to exceed 0.4 weight percent of the coating.

(c) *Optional processing.* Poly- tetrafluoroethylene resins may be irradiated by either a cobalt-60 sealed source, at a maximum dose of gamma radiation not to exceed 7.5 megarads, or an electron beam at energy levels not to exceed 2.5 million electron volts with a maximum dosage of 7.5 megarads, to produce lubricant powders having a particle diameter of not more than 20 microns for use only as components of articles intended for repeated use in contact with food.

(d) *Specifications*—(1) *Infrared identification.* Perfluorocarbon resins can be identified by their characteristic infrared spectra.

(2) *Melt-viscosity.* (i) The perfluorocarbon resins identified in paragraph (a)(1) of this section shall have a melt viscosity of not less than 10^4 poises at 380° C (716° F) as determined by ASTM method D1238–82, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The melt viscosity of the perfluorocarbon resins identified in paragraph (a)(1) of this section shall not vary more than 50 percent within one-half hour at 380° C (716° F).

(ii) Perfluorocarbon resins identified in paragraph (a)(2) of this section shall have a melt viscosity of not less than 10^4 poises at 372° C (702° F) as determined by a more detailed method titled "Determination of Melt Viscosity, Molecular Weight Distribution Index and Viscosity Stability," which is incorporated by reference. Copies are available from the Division of Food and Color Additives (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) *Thermal instability index.* The thermal instability index of the tetrafluoroethylene homopolymer shall not exceed 50 as determined by ASTM method D1457–56T, "Test for Thermal Instablility index of Tetrafluoroethylene Homopolymer" (Revised 1956), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The requirements of this paragraph do not apply to polytetrafluoroethylene resin lubricant powders described in paragraph (c) of this section.

(e) *Limitations.*[1] (*1*) *Perfluorocarbon-molded articles having a surface*

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[1] A more detailed procedure of extraction conditions is entitled, "Preparation of Extracts," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

area of 6.45 square decimeters (100 square inches) or more and at least 1.27 millimeters (0.05 inch) thick shall be extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, n-heptane, and ethyl acetate.

(2) Perfluorocarbon resins identified in paragraphs (a)(1) and (2) of this section and intended for use as coatings or components of coatings shall meet extractability limits prescribed in paragraph (e)(3) of this section when the resins in the form of coatings described in paragraphs (e)(2) (i) and (ii) of this section are extracted at reflux temperatures for 2 hours separately with distilled water, 8 percent ethanol, and *n*-heptane:

(i) Perfluorocarbon resin coatings based on resins identified in paragraph (a)(1) of this section shall be applied to both sides of a 0.025-millimeter (0.001 inch) thick aluminum foil to a thickness of 0.025 millimeter (0.001 inch) after thermal curing at 399° C (750° F) for 10 minutes. If a primer is used, the total thickness of the primer plus topcoat shall equal 0.025 millimeter (0.001 inch) after heat curing.

(ii) Perfluorocarbon resin coatings based on resins identified in paragraph (a)(2) of this section shall be applied to both sides of a 0.025-millimeter (0.001 inch) thick aluminum foil to a thickness of 0.10 millimeter (0.004 inch) after thermal curing at 427° C (800° F) for 10 minutes. If a primer is used, the total thickness of the primer plus topcoat shall equal 0.10 millimeter (0.004 inch) after heat curing.

(3) The extracted surfaces shall meet the following extractability limits:

(i) Total extractives not to exceed 3.1 milligrams per square decimeter (0.2 milligram per square inch).

(ii) Fluoride extractives calculated as fluorine not to exceed 0.46 milligram per square decimeter (0.03 milligram per square inch).

(f) *Conditions of use.* Perfluorocarbon resins identified in paragraph (a)(2) of this section are limited to use as coatings or components of coatings for articles intended for repeated food-contact use.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348; secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[43 FR 44834, Sept. 29, 1978, as amended at 47 FR 11843, Mar. 19, 1982; 47 FR 14699, Apr. 6, 1982; 49 FR 10109, Mar. 19, 1984; 50 FR 1502, Jan. 11, 1985]

§ 177.1560 Polyarylsulfone resins.

Polyarylsulfone resins (CAS Reg. No. 79293-56-4) may be safely used as articles or components of articles intended for use in contact with food, at temperatures up to and including normal baking temperatures, in accordance with the following prescribed conditions:

(a) *Identity.* Polyarylsulfone resins are copolymers containing not more than 25 percent of oxy-*p*-phenylene-oxy-*p*-phenylenesulfonyl-*p*-phenylene polymer units and not less than 75 percent of oxy-*p*-phenylenesulfonyl-*p*-phenylene-oxy-*p*-phenylenesulfonyl-*p*-phenylene polymer units. The copolymers have a minimum reduced viscosity of 0.40 deciliter per gram in 1-methyl-2-pyrrolidinone in accordance with ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St., NW., Washington, DC 20408.

(b) *Optional adjuvant substances.* The basic polyarylsulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 179 of this chapter, substances generally recognized as safe in food, substances used in accordance with a prior sanction of approval, and substances named in this paragraph and further identified as required:

Substances	Limitations
Sulfolane	Not to exceed 0.15 percent as residual solvent in the finished basic resin.

(c) *Extractive limitations.* The finished polyarylsulfone resin when extracted for 2 hours with the following solvents at the specified temperatures yields total extractives in each extracting solvent not to exceed 0.008 milligram per square centimeter of food-contact surface: distilled water at 121 °C (250 °F), 50 percent (by volume) ethyl alcohol in distilled water at 71.1 °C (160 °F), 3 percent acetic acid in distilled water at 100 °C (212 °F), and *n*-heptane at 65.6 °C (150 °F).

NOTE: In testing the finished polyarylsulfone resin use a separate test sample for each required extracting solvent.

[50 FR 31046, July 24, 1985]

§ 177.1570 Poly-1-butene resins and butene/ethylene copolymers.

The poly-1-butene resins and butene/ethylene copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* Poly-1-butene resins are produced by the catalytic polymerization of 1-butene liquid monomer. Butene/ethylene copolymers are produced by the catalytic polymerization of 1-butene liquid monomer in the presence of small amounts of ethylene monomer so as to yield no higher than a 6-weight percent concentration of polymer units derived from ethylene in the copolymer.

(b) *Specifications and limitations.* Poly-1-butene resins and butene/ethylene copolymers shall conform to the specifications prescribed in paragraph (b)(1) of this section, and shall meet the extractability limits prescribed in paragraph (b)(2) of this section.

(1) *Specifications*—(i) *Infrared identification.* Poly-1-butene resins and butene/ethylene copolymers can be identified by their characteristic infrared spectra.

(ii) *Viscosity.* Poly-1-butene resins and the butene/ethylene copolymers have an intrinsic viscosity 1.0 to 3.2 as determined by ASTM method D1601-78, "Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(iii) *Density.* Poly-1-butene resins have a density of 0.904 to 0.920 gms/cm^3, and butene/ethylene copolymers have a density of 0.890 to 0.916 gms/cm^3 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(iv) *Melt index.* Poly-1-butene resins have a melt index of 0.1 to 24 and the butene/ethylene copolymers have a melt index of 0.1 to 20 as determined by ASTM method D1238-82, condition E, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(2) *Limitations.* Poly-1-butene resins and butene/ethylene copolymers for use in articles that contact food, and for articles used for packing or holding food during cooking shall yield no more than the following extractables:

(i) Poly-1-butene resins may be used as articles or components of articles intended for use in contact with food, provided that the maximum extractables do not exceed 2.5 percent by weight of the polymer when film or molded samples are tested for 2 hours at 50 °C (122 °F) in *n*-heptane.

(ii) Butene/ethylene copolymers containing no more than 6 percent by weight of polymer units derived from ethylene may be used as articles or components of articles intended for contact with food under conditions of use B, C, D, E, F, G, or H described in Table 2 of § 176.170(c) of this chapter, subject to the provisions of this section and provided that the maximum extractables from test films 0.1 to 0.2 millimeter (0.004 to 0.008 inch) in thickness do not exceed 0.80 percent by weight of the polymer when extracted in a soxhlet extractor for 6 hours with refluxing 95 percent ethanol.

(iii) Poly-1-butene resins may be used as articles or components of articles intended for packaging or holding food during cooking, provided that the thickness of such polymers in the form in which they contact food shall not exceed 0.1 millimeter (0.004 inch) and yield maximum extractables of not more than 2.5 percent by weight of the polymer when films are extracted for 2 hours at 50 °C (122 °F) in *n*-heptane.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984; 50 FR 31349, Aug. 2, 1985]

§ 177.1580 Polycarbonate resins.

Polycarbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Polycarbonate resins are polyesters produced by:

(1) The condensation of 4,4′-isopropylidenediphenol and carbonyl chloride to which may have been added certain optional adjuvant substances required in the production of the resins; or by

(2) The reaction of molten 4,4′-isopropylidenediphenol with molten diphenyl carbonate in the presence of the disodium salt of 4,4′-isopropylidenediphenol.

(3) The condensation of 4,4′-isopropylidenediphenol, carbonyl chloride, and 0.5 percent weight maximum of α2,α6-bis (6-hydroxy-*m*-tolyl) mesitol to which may have been added certain optional adjuvant substances required in the production of branched polycarbonate resins.

(b) The optional adjuvant substances required in the production of resins produced by the methods described in paragraph (a)(1) and (3) of this section may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
p-tert-Butylphenol	
Chloroform	
Ethylene dichloride	
Heptane	
Methylene chloride	
Monochlorobenzene	Not to exceed 500 p.p.m. as residual solvent in finished resin.
Phenol (CAS Reg. No. 108-95-2).	
Pyridine	
Toluene (CAS Reg. No. 108-88-3).	Not to exceed 800 parts per million as residual solvent in finished resin.
Triethylamine	

(c) Polycarbonate resins shall conform to the specification prescribed in paragraph (c)(1) of this section and shall meet the extractives limitations prescribed in paragraph (c)(2) of this section.

(1) *Specification.* Polycarbonate resins can be identified by their characteristic infrared spectrum.

(2) *Extractives limitations.* The polycarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10.

(i) Polycarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(ii) Polycarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(iii) Polycarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 23227, Apr. 24, 1981; 49 FR 4372, Feb. 6, 1984; 50 FR 14096, Apr. 10, 1985]

§ 177.1590 Polyester elastomers.

The polyester elastomers identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in § 176.170(c) of this chapter, Table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyester elastomers are those produced by the ester exchange reaction when one or more of the following phthalates—dimethyl terephthalate, dimethyl orthophthalate, and dimethyl isophthalate—is made to react with alpha-hydroomega-hydroxypoly (oxytetramethylene) and/or 1,4-butanediol such that the finished elastomer has a number average molecular weight between 20,000 and 30,000.

(b) Optional adjuvant substances employed in the production of the polyester elastomers or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
4,4' - Bis (*alpha, alpha*-dimethyl-benzyl) diphenylamine	For use only as an antioxidant.
Tetrabutyl titanate	For use only as a catalyst.

(c) An appropriate sample of the finished polyester elastomer in the form in which it contacts food when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using No. 50 emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 100 liters per mil of thickness.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984]

§ 177.1595 Polyetherimide resin.

The polyetherimide resin identified in this section may be safely used as an article or component of an article intended for use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, the polyetherimide resin is 1,3-isobenzofurandione, 5,5'[(1-methylethylidene)bis(4,1-phenyleneoxy)] bispolymer with 1,3-benzenediamine (CAS Reg. No. 61128-46-9), and is derived from the condensation reaction of *m*-phenylenediamine and bisphenol A-dianhydride.

(b) *Optional adjuvants.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of basic resins or finished food-contact articles. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for such use by applicable regulations as set forth in Part 174 of this chapter.

(c) *Specifications and extractives limitations*—(1) *Specifications.* Polyetherimide resin identified in paragraph (a) of this section shall have an intrinsic viscosity in chloroform at 25 °C (77 °F) of not less than 0.35 deciliter per gram as determined by a method titled "Intrinsic Viscosity of ULTEM Polyetherimide Using Chloroform as the Solvent," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Extractive limitations.* Extractive limitations are applicable to the basic polyetherimide resin in the form of molded discs of thickness 0.16 centimeter (0.063 inch). The resin discs when extracted with distilled water at 121 °C (250 °F) for 2 hours yield total nonvolatile extractives of not more than 12.3 micrograms per square centimeter.

[50 FR 31351, Aug. 2, 1985; 50 FR 35535, Sept. 3, 1985]

§ 177.1600 Polyethylene resins, carboxyl modified.

Carboxyl-modified polyethylene resins may be safely used as the food-contact surface of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, carboxyl-modified polyethylene resins consist of basic polymers produced when etylene-methyl acrylate basic copolymers, containing no more than 25 weight percent of polymer units derived from methyl acrylate, are made to react in an aqueous medium with one or more of the following substances:

Ammonium hydroxide.
Calcium carbonate.
Potassium hydroxide.
Sodium hydroxide.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in § 176.170(d) of this chapter; and if the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178, and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

(c) The provisions of paragraph (b) of this section are not applicable to carboxyl-modified polyethylene resins used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1610 Polyethylene, chlorinated.

Chlorinated polyethylene identified in this section may be safely used as articles or components of articles that contact food, except for articles used for packing or holding food during cooking, subject to the provisions of this section.

(a) For the purpose of this section, chlorinated polyethylene consists of basic polymers produced by the direct chlorination of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.1 of the table in § 177.1520(c). Such chlorinated polyethylene contains a maximum of 60 percent by weight of total chlorine, as determined by ASTM method D1303-55 (Reapproved 1979), "Standard Test Method for Total Chlorine in Vinyl Chloride Polymers and Copolymers," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and has a 7.0 percent maximum extractable fraction in *n*-hexane at 50° C, as determined by the method in contact with all types of food, except that when used in contact with fatty food of Types III, IV-A, V, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter, chlorinated polyethylene is limited to use only as a modifier admixed at levels not exceeding 15 weight percent in plastic articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 177.1980.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984]

§ 177.1615 Polyethylene, fluorinated.

Fluorinated polyethylene, identified in paragraph (a) of this section, may be safely used as food-contact articles in accordance with the following prescribed conditions:

(a) Fluorinated polyethylene food-contact articles are produced by modifying the surface of polyethylene articles through action of fluorine gas in combination with gaseous nitrogen as an inert diluent. Such modification affects only the surface of the polymer, leaving the interior unchanged. Fluorinated polyethylene articles are manufactured from basic resins containing not less than 85 weight-percent of polymer units derived from ethylene and identified in § 177.1520 (a)(2) and (3)(i).

(b) Fluorinated polyethylene articles conform to the specifications and use limitations of § 177.1520(c), items 2.1 and 3.1.

(c) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields fluoride ion not to exceed 5 parts per million calculated on the basis of the volume of food held by the food-contact article.

[48 FR 39057, Aug. 29, 1983]

§ 177.1620 Polyethylene, oxidized.

Oxidized polyethylene identified in paragraph (a) of this section may be safely used as a component of food-contact articles, in accordance with the following prescribed conditions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.3 of the table in § 177.1520(c). Such oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry, contains a maximum of 5 percent by weight of total oxygen, and has an acid value of 9 to 19.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in § 177.1330(c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with § 176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in § 176.170(d)(5)(iii)(*b*) of this chapter. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by such regulations. (NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.)

(c) The provisions of this section are not applicable to oxidized polyethylene used as provided in §§ 175.105 and 176.210 of this chapter, and § 177.2800. The provisions of paragraph (b) of this section are not applicable to oxidized polyethylene used as provided in §§ 175.125 and 176.170(a)(5) of this chapter and § 177.1200.

§ 177.1630 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer or ethylene terephthalate-isophthalate of copolymers, to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

(c)(1) Polyethylene phthalate spunbonded nonwoven fabric consist of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbond-

ed fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitations further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any specification in such regulation.

(e) Substances employed in the production of polyethylene phthalate plastics include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in polyethylene phthalate plastics and used in accordance with such sanction or approval.

(3) Substances which by regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter may be safely used as components of resinous or polymeric food-contact surfaces subject to the provisions of such regulation.

(4) Substances identified in this paragraph (e)(4) subject to the limitations prescribed:

LIST OF SUBSTANCES AND LIMITATIONS

(i) Base sheet:

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid.

Ethylene terephthalate-isophthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid and dimethyl isophthalate or isophthalic acid with ethylene glycol. The finished copolymers contain either (*a*) 77-83 weight percent or (*b*) at least 98 weight percent of polymer units derived from ethylene terephthalate. Copolymers containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate are limited to use with food of types I, II, IV-B, VI-B, VII-B, and VIII as described in Table 1 of § 176.170(c) of this chapter and under use conditions E, F, and G, as described in Table 2 of § 176.170(c) of this chapter.

(ii) Base sheet and base polymer:

Ethylene terephthalate polymer: Prepared by the condensation of dimethyl terephthalate and ethylene glycol.

Ethylene terephthalate polymer: Prepared by the condensation of terephthalic acid and ethylene glycol.

(iii) Coatings:

Ethylene azelate-terephthalate copolymer: The copolymer, dissolved in 1,1,2-trichloroethane and/or methylene chloride, may be used as a heat-activated sealant on polyethylene terephthalate film intended for sealing polyethylene terephthalate pouches that are used as containers of either nonalcoholic beverages or alcoholic beverages containing not more than 15 percent ethyl alcohol. The copolymer has a terephthalate/azelate molecular ratio of 1.25/1.00 and a relative viscosity of not less than 1.5 as determined by a method title "General Procedure of Determining the Relative Viscosity of Resin Polymers," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection, at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Total residual copolymer solvent (1,1,2-trichloroethane and/or methylene chloride) shall not exceed 0.13 milligram per square inch of film, and food contact of the film shall be limited to not more than 1 square inch per 250 grams of beverage.

2-Ethylhexyl acrylate copolymerized with one or more of the following:
  Acrylonitrile.
  Methacrylonitrile.
  Methyl acrylate.
  Methyl methacrylate.
  Itaconic acid.

Vinylidene chloride copolymerized with one or more of the following:
  Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.
  Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.
  Acrylonitrile.
  Methacrylonitrile.
  Vinyl chloride.
  Itaconic acid.

Styrene-maleic anhydride resin, partial 2-butoxyethyl ester, ammonium salt (CAS Reg. No. 68890-80-2). For use only as a coating for polyethylene phthalate films complying with paragraph (a) of this section, at levels not to exceed 0.025 gram per square meter (0.016 milligram per square inch) of the film, in contact with food of types VIII and IX in Table 1 of

§ 176.170(c) of this chapter, under use conditions E, F, and G in Table 2 of § 176.170(c) of this chapter.

(iv) Emulsifiers:

Sodium dodecylbenzenesulfonate: As an adjuvant in the application of coatings to the base sheet or base polymer.

Sodium lauryl sulfate: As an adjuvant in the application of coatings to the base sheet or base polymer.

2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on polyethylene phthalate film under conditions of use E, F, and G described in table 2 of § 175.300(d) of this chapter, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

(v) Modifier:

1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol and *α*-hydro-*omega*-hydroxypoly(oxy-1,4-butanediyl) CAS Reg. No. 9078-71-1) meeting the following specifications:

Melting point: 200° to 215° C as determined by ASTM method D2117-82, "Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Density: 1.15 to 1.20 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

The modifier is used at a level not to exceed 5 percent by weight of polyethylene terephthalate film. The average thickness of the finished film shall not exceed 0.016 millimeter (0.0006 inch).

Hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) meeting the specifications in § 177.1500(b), item 10, when tested by the methods given in § 177.1500(c). The modifier is used in polyethylene terephthalate at a level not to exceed 30 percent by weight of the polyethylene terephthalate.

Chloroform-soluble extractives shall not exceed 0.08 milligram/centimeter ^{2} (0.5 milligram/inch ^{2}) of food-contact surface of the modified polyethylene terephthalate article when exposed to the following solvents at temperatures and times indicated:

(*a*) Distilled water at 49 °C (120 °F) for 24 hours;

(*b*) *n*-Heptane at 49 °C (120 °F) for 24 hours,

(*c*) 8 percent ethyl alcohol at 49 °C (120 °F) for 24 hours.

For use in contact with all types of foods except (*a*) those containing more than 8 percent alcohol, or (*b*) those at temperatures over 49 °C (120 °F).

(f) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (f)(1) of this section are used as provided in paragraph (f)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250° F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in ^{2} of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150°F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in ^{2} of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250° F.

(g) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section; and

(ii) The food contact surface when exposed to 50 percent ethyl alcohol at 120° F for 24 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in ^{2} of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic beverages that do not exceed 50 percent alcohol by volume.

(h) Uncoated polyethylene phthalate plastics consisting of a base sheet or base polymer prepared as prescribed from substances identified in paragraphs (e)(4)(i) and (ii) of this section and conforming with the specifications prescribed in paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250° F for 2 hours yields chloroform-soluble extractives not to exceed 0.02 milligram/inch^2 of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150° F for 2 hours, yields chloroform-soluble extractives not to exceed 0.02 milligram/inch^2 of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used to contain foods during oven baking or oven cooking at temperatures above 250° F.

(i) Polyethylene phthalate fabric, identified in paragraph (c) of this section and conforming with the specifications prescribed in paragraph (i)(1) of this section, is used only as provided in paragraph (i)(2) of this section.

(1) *Specifications.* Chloroform-soluble extractives shall not exceed 0.2 milligram/inch^2 of food-contact surface when exposed to the following solvents at temperatures and times indicated:

(i) Distilled water at 212° F for 2 hours.

(ii) *n*-Heptane at 150° F for 2 hours.

(iii) 50 percent ethyl alcohol at 120° F for 24 hours.

(2) *Conditions of use.* The plastics are intended for:

(i) Dry food contact.

(ii) Bulk food (excluding alcoholic beverages) repeated use applications, including filtration, at temperatures not exceeding 212° F.

(iii) Filtration of bulk alcoholic beverages, not exceeding 50 percent alcohol by volume, at temperatures not exceeding 120° F.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348; secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 18611, Apr. 8, 1977; 44 FR 40886, July 13, 1979; 45 FR 6541, Jan. 29, 1980; 47 FR 11844, Mar. 19, 1982; 47 FR 53346, Nov. 26, 1982; 48 FR 30361, July 1, 1983; 49 FR 10110, Mar. 19, 1984; 50 FR 31047, July 24, 1985; 51 FR 3772, Jan. 30, 1986]

§ 177.1635 Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene).

Poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) identified in this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section:

(a) *Identity.* For the purposes of this section, poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) are basic polymers, manufactured as described in this paragraph, meeting the specifications prescribed in paragraph (c) of this section.

(1) Poly(*p*-methylstyrene) (CAS Reg. No. 24936-41-2) polymer produced by the polymerization of *p*-methylstyrene.

(2) Rubber-modified poly(*p*-methylstyrene) (CAS Reg. No. 33520-88-6) polymer produced by combining styrene-butadiene copolymer and/or polybutadiene with poly(*p*-methylstyrene), either during or after polymerization of the poly(*p*-methylstyrene), such that the finished polymers contain not less than 75 weight percent of total polymer units derived from *p*-methylstyrene) monomer.

(b) *Optional adjuvants.* The basic polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by applicable regulations in this chapter, substances generally recognized as safe in food, substances generally recognized as safe in indirect additives, and substances used in accordance with prior sanction or approval.

(c) *Specifications.* (1) Poly(*p*-methylstyrene) basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight percent of total residual *p*-methystyrene monomer, as determined by a gas chromatographic method titled, "Gas Chromatographic Determination of PMS and PET in PPMS Basic Polymers," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Rubber-modified poly(*p*-methylstyrene) basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual *p*-methylstyrene monomer, as determined by the method identified in paragraph (c)(1) of this section

(d) *Other specifications and limitations.* The poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(e) *Conditions of use.* Poly(*p*-methylstyrene) basic polymers and rubber-modified poly(*p*-methylstyrene) basic polymers identified in paragraph (a)(1) and (2), respectively, of this section shall only be used in contact with foods described as Types I, II, IV-B, VI, VII-B, and VIII, in Table 1 of § 176.170(c) of this chapter, and only under conditions of use E, F, and G set forth in Table 2 of § 176.170(c) of this chapter.

[48 FR 31384, July 8, 1983]

§ 177.1640 Polystyrene and rubber-modified polystyrene.

Polystyrene and rubber-modified polystyrene identified in this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, polystyrene and rubber-modified polystyrene are basic polymers manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (c) of this section when tested by the method described in paragraph (d) of this section.

(1) Polystyrene consists of basic polymers produced by the polymerization of styrene.

(2) Rubber-modified polystyrene consists of basic polymers produced by combining styrene-butadiene copolymers and/or polybutadiene with polystyrene, either during or after polymerization of the polystyrene, such that the finished basic polymers contain not less than 75 weight percent of total polymer units derived from styrene monomer.

(b) *Optional adjuvants.* The basic polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications.* (1) Polystyrene basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section, except that when used in contact with fatty foods of Types III, IV-A, V, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter, such polystyrene basic polymers shall contain not more than 0.5 weight percent of total residual styrene monomer.

(2) Rubber-modified polystyrene basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section.

(d) *Analytical method for determination of total residual styrene monomer content*—(1) *Scope.* This method is suitable for the determination of residual styrene monomer in all types of styrene polymers.

(2) *Principle.* The sample is dissolved in methylene chloride. An aliquot of the solution is injected into a gas chromatograph. The amount of styrene monomer present is determined from the area of the resulting peak.

(3) *Apparatus*—(i) *Gas chromatograph.* Beckman GC-2A gas chromato-

graph with hydrogen flame detector or apparatus of equivalent sensitivity.

(ii) *Chromatograph column.* One-quarter inch outside diameter stainless steel tubing (0.028 inch wall thickness), 4 feet in length, packed with 20 percent polyethylene glycol (20,000 molecular weight) on alkaline treated 60-80 mesh firebrick.

(iii) *Recorder.* Millivolt range of 0-1, chart speed of 30 inches per hour.

(4) *Reagents.* Compressed air, purified; helium gas; hydrogen gas; methylene chloride, redistilled; and styrene monomer, redistilled.

(5) *Operating conditions for the gas chromatograph.* (i) The column is operated at a temperature of 100° C with a helium flow rate of 82 milliliters per minute.

(ii) The hydrogen burner is operated with 15 pounds per square inch of air pressure and 7 pounds per square inch of hydrogen pressure.

(iii) The attenuation of the hydrogen flame detector is set at 2×10^2.

(6) *Standardization.* (i) Prepare a standard solution by weighing accurately 15 to 20 milligrams of styrene monomer into a 2-ounce bottle containing 25.0 milliliters of methylene chloride. Cap the bottle tightly and shake to thoroughly mix the solution.

(ii) By means of a microliter syringe, inject 1 microliter of the standard solution into the gas chromatograph. Measure the area of the styrene monomer peak which emerges after approximately 12 minutes.

(7) *Procedure.* (i) Transfer 1 gram of sample (accurately weighed to the nearest 0.001 gram to a 2-ounce bottle and add several glass beads. Pipette 25.0 milliliters of methylene chloride into the bottle. Cap the bottle tightly and place on a mechanical shaker. Shake until the polymer is completely dissolved. If any insoluble residue remains, allow the bottle to stand (or centrifuge at a low speed) until a clear supernatant layer appears.

(ii) By means of a microliter syringe, inject 3 microliters of the clear supernatant liquid into the gas chromatograph.

(iii) Measure the area of the resulting styrene monomer peak. Compare the sample peak area with the area produced by the standard styrene monomer solution. Calculation:

Percent residual styrene monomer = Milligrams monomer in standard × peak area of sample/Peak area of monomer standard × sample weight in grams × 30

(e) *Other specifications and limitations.* The polystyrene and rubber-modified polystyrene identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) *Nonapplicability.* The provisions of this section are not applicable to polystyrene and rubber-modified polystyrene used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1650 Polysulfide polymer-polyepoxy resins.

Polysulfide polymer-polyepoxy resins may be safely used as the food-contact surface of articles intended for packaging, transporting, holding, or otherwise contacting dry food, in accordance with the following prescribed conditions:

(a) Polysulfide polymer-polyepoxy resins are the reaction products of liquid polysulfide polymers and polyfunctional epoxide resins, cured with the aid of tri(dimethylaminomethyl) phenol, to which have been added certain optional substances to impart desired technological properties to the resins. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in this part, prior sanctions, or approvals.

(3) Substances named in this subparagraph and further identified as required:

List of substances	Limitations
Bis(2-chloroethyl) formal	
Bis(dichloropropyl) formal	Cross-linking agent.
Butyl alcohol	Solvent.
Carbon black (channel process)	
Chlorinated paraffins	Cross-linking agent.
Epoxidized linseed oil	
Epoxidized soybean oil	
Epoxy resins (as listed in § 175.300(b)(3)(viii)(*a*) of this chapter).	
Ethylene glycul monobutyl ether	Solvent.
Magnesium chloride	
Methyl isobutyl ketone	Solvent
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Sodium dibutyl naphthalene sulfonate.	Wetting agent.
Sodium hydrosulfide	
Sodium polysulfide	
$\beta,\beta',\gamma,\gamma'$-Tetrachloro normal propyl ether.	Cross-linking agent.
Titanium dioxide	
Toluene	Solvent.
Trichloroethane	Cross-linking agent.
1,2,3-Trichloropropane	Do
Urea-formaldehyde resins	
Xylene	Solvent.

(b) The resins are used as the food-contact surface for dry food.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit and abrasion coefficient of not less than 20 liters per mil of film thickness.

(Secs. 409, 701(e), 706, 76 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1655 Polysulfone resins.

Polysulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polysulfone resins (poly(oxy-*p*-phenylenesulfonyl-*p*-phenyleneoxy-*p*-phenyleneisopropylidene-*p*-phenylene)resins) (CAS Reg. No. 25154-01-2) consist of basic resins produced when the disodium salt of 4,4′-isopropylidenediphenol is made to react with 4,4′ dichlorodiphenyl sulfone in such a way that the finished resins have a minimum number average molecular weight of 15,000, as determined by osmotic pressure in monochlorobenzene.

(b) The basic polysulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic polysulfone resins may include substances described in § 174.5(d) of this chapter and the following:

List of substances	Limitations
Dimethyl sulfoxide.	Not to exceed 50 parts per million as residual solvent in finished basic resin.
Monochlorobenzene.	Not to exceed 500 parts per million as residual solvent in finished basic resin.

(c) Polysulfone resins, when extracted at reflux temperatures for 6 hours with the solvents—distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane, yield total extractives in each extracting solvent not to exceed 0.0078 milligram per square centimeter (0.05 milligram per square inch) of resin surface. Note: In testing the finished polysulfone resins, use a separate resin test sample for each required extracting solvent.

(d) Polysulfone resins intended for repeated use in contact with food may be used under conditions of use A through H in Table 2 of § 176.170(c) of this chapter. The resins intended for single-service food-contact use may be used only under condition of use H described in Table 2 of § 176.170(c) of this chapter.

[51 FR 882, Jan. 9, 1986; 51 FR 4165, Feb. 3, 1986]

§ 177.1660 Poly (tetramethylene terephthalate).

Poly(tetramethylene terephthalate) (poly (oxytetramethyleneoxyterephthaloyl)) [Chemical Abstracts Service Registry No. 24968-12-5] identified in this section may be safely used as articles or components of articles intended to contact food, in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, poly (tetramethylene terephthalate) is the reaction product of dimethyl terephthalate with 1,4-butanediol to which may have been added certain optional substances to impart desired technological properties to the polymer.

(b) *Optional adjuvant substances.* Poly(tetramethylene terephthalate) identified in paragraph (a) of this section may contain optional adjuvant substances. The quantity of any optional adjuvant substance employed in the production of the polymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, and substances permitted under applicable regulations in this part.

(c) *Specifications.* (1) Inherent viscosity of a 0.50 percent solution of the polymer in phenol/tetrachloroethane (60/40 weight ratio) solvent is not less than 0.8 as determined using a Wagner viscometer (or equivalent) and calculated from the following equation:

Inherent viscosity = (natural logarithm of N_r)/(c)

where:

N_r = Ratio of flow time of the polymer solution to that of the solvent and

c = polymer concentration of the test solution in grams per 100 milliliters.

(2) Poly(tetramethylene terephthalate) in the finished form in which it is to contact food shall yield total extractives as follows:

(i) Not to exceed 0.08 milligram per square inch of food contact surface when extracted for 2 hours at 250° F with distilled water.

(ii) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 150° F with *n*-heptane.

(iii) Not to exceed 0.04 milligram per square inch of food contact surface when extracted for 2 hours at 212° F with 3 percent aqueous acetic acid.

(iv) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 65.6 °C (150 °F) with 50 percent ethanol.

[42 FR 14572, Mar. 15, 1977, as amended at 50 FR 20748, May 20, 1985]

§ 177.1670 Polyvinyl alcohol film.

Polyvinyl alcohol film may be safely used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Types V, VIII, and IX, in accordance with the following prescribed conditions:

(a) The polyvinyl alcohol film is produced from polyvinyl alcohol having a minimum viscosity of 4 centipoises when a 4-percent aqueous solution is tested at 20° C.

(b) The finished food-contact film for use in contact with Food Types V or IX, when extracted with the solvent characterizing the type of food and under the conditions of time and temperature characterizing its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields total extractives not to exceed 0.078 milligram per square centimeter (0.5 milligram per square inch) of food-contact surface when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The finished food-contact film shall not be used as a component of food containers intended for use in contact with water.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1680 Polyurethane resins.

The polyurethane resins identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in § 176.170(c) of this chapter, Table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyurethane resins are those produced when one or more of the isocyanates listed in paragraph (a)(1) of this section is made to react with one or more of the substances listed in paragraph (a)(2) of this section:

(1) Isocyanates:

Bis(isocyanatomethyl) benzene (CAS Reg. No. 25854-16-4).
Bis(isocyanatomethyl) cyclohexane (CAS Reg. No. 38661-72-2).
4,4′-Diisocyanato-3,3′-dimethylbiphenyl (bitolylene diisocyanate).
Diphenylmethane diisocyanate.
Hexamethylene diisocyanate.
3-Isocyanatomethyl - 3,5,5 - trimethylcyclohexyl isocyanate.
4,4-Methylenebis(cyclohexyl isocyanate).
Toluene diisocyanate.

(2) List of substances:

Adipic acid.
1,4-Butanediol.
1,3-Butylene glycol.
2,2-Dimethyl-1,3-propanediol.
Ethylene glycol.
α-Hydro-*omega*-hydroxypoly (oxytetramethylene).
α,α′- (Isopropylidenedi - *p* - phenylene)bis [*omega* -hydroxypoly (oxypropylene)(3-4 moles)], average molecular weight 675.
Maleic anhydride.
α,α′,α″,α‴-Neopentanetetrayltetrakis [*omega*- hydroxypoly (oxypropylene) (1-2 moles)], average molecular weight 400.
Pentaerythritol-linseed oil alcoholysis product.
Phthalic anhydride.
Polybutylene glycol.
Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.
Poly(oxycarbonylpentamethylene).
Polyoxypropylene ethers of 4,4′-isopropylidenediphenol (containing an average of 2-4 moles of propylene oxide).
Polypropylene glycol.
α,α′,α″-1,2,3-Propanetriyltris [*omega*-hydroxypoly (oxypropylene) (15-18 moles)], average molecular weight 3,000.
Propylene glycol.
α,α′,α″-[Propylidynetris (methylene)] tris [*omega*-hydroxypoly (oxypropylene) (minimum 1.5 moles)], minimum molecular weight 400.
α-[*p*(1,1,3,3-Tetramethylbutyl) - phenyl]- *omega* - hydroxypoly(oxyethylene) (5 moles), average molecular weight 425.
Trimethylol propane.

(b) Optional adjuvant substances employed in the production of the polyurethane resins or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
1-[(2-Aminoethyl)amino]2-propanol	As a curing agent.
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	As a preservative.
Dibutyltin diacetate	As a catalyst.
Dibutyltin dichloride	Do.
Dibutyltin dilaurate	Do.
N,N-Dimethyldodecylamine	Do.
N-Dodecylmorpholine	Do.
α,α′-[Isopropylidenebis[*p*-phenyleneoxy(2-hydroxytrimethylene)]]bis[*omega*-hydroxypoly-(oxyethylene) (136-170 moles)], average molecular weight 15,000.	As a stabilizer.
4,4′-Methylenedianiline	As a curing agent.
1,1′,1″-Nitrilotri-2-propanol	Do.
2,2′-(*p*-Phenylenedioxy) diethanol	Do.
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160)	As a pigment.
Polyvinyl isobutyl ether	
Polyvinyl methyl ether	
Soyealkyd resin	Conforming in composition with § 175.300 of this chapter and containing litharge not to exceed that residual from its use as the reaction catalyst and creosol not to exceed that required as an antioxidant.
N,N,N′,N′-Tetrakis (2-hydroxypropyl)ethylenediamine	As a curing agent.
Triethanolamine	Do.

List of substances	Limitations
Trimethyleneglycol di (*p*-aminobenzoate) (CAS Reg No 57609-64-0)	As a curing agent
Ultramarine blue	As a pigment

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

(Secs. 201(s) 409, 72 Stat. 1784-1788 as amended(21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 57033, Nov. 20, 1981; 49 FR 10110, Mar. 19, 1984; 50 FR 51847, Dec. 20, 1985]

§ 177.1810 Styrene block polymers.

The styrene block polymers identified in paragraph (a) of this section may be safely used as articles or as components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene block polymers are basic polymers manufactured as described in this paragraph, so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(1) Styrene block polymers with 1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene.

(2) Styrene block polymers with 2-methyl-1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 2-methyl-1,3-butadiene.

(3) Styrene block polymers with 1,3-butadiene, hydrogenated are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene, and subsequently hydrogenated.

(b) Specifications:

Styrene block polymers	Molecular weight (minimum)	Solubility	Glass transition points	Maximum extractable fraction in distilled water at specified temperatures, times, and thicknesses	Maximum extractable fraction in 50 percent ethanol at specified temperatures, times, and thicknesses
1 (i) Styrene block polymers with 1,3-butadiene, for use as articles or as components of articles that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in Table 1 in § 176.170(c) of this chapter under conditions of use D, E, F, and G described in Table 2 in § 176.170(c) of this chapter	29,000	Completely soluble in toluene	−98 °C (−144 °F) to −71 °C (−96 °F) and 86 °C (187 °F) to 122 °C (252 °F)	0.0039 mg/cm^2 (0.025 mg/in^2) of surface at reflux temperature for 30 min on a 0.19 cm (0.075 in) thick sample	0.002 mg/cm^2 (0.01 mg/in^2) of surface at 66 °C (150 °F) for 2 hr on a 0.19 cm (0.075 in) thick sample

Styrene block polymers	Molecular weight (minimum)	Solubility	Glass transition points	Maximum extractable fraction in distilled water at specified temperatures, times, and thicknesses	Maximum extractable fraction in 50 percent ethanol at specified temperatures, times, and thicknesses
(ii) Styrene block polymers with 1,3-butadiene; for use as components of pressure-sensitive adhesives that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in Table 1 in § 176.170(c) of this chapter under conditions of use C, D, E, F and G described in Table 2 in § 176.170(c) of this chapter, provided the pressure-sensitive adhesives be applied only to closure tapes for sealing containers having a capacity of not less than 160 cc (5.5 fluid ounces) and that the area of the adhesive exposed to food shall not exceed 4.03 cm^2 (0.625 in^2). The pressure-sensitive adhesive may contain terpene resins as identified in § 175.125(b)(2) of this chapter.	29,000	do	do	do	Do.
2. Styrene block polymers with 2-methyl-1,3-butadiene; for use as articles or as components of articles that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in Table 1 in § 176.170(c) of this chapter.	29,000	do	−65 °C (−85 °F) to −47 °C (−53 °F) and 86 °C (187 °F) to 122 °C (252 °F).	0.002 mg/cm^2 (0.01 mg/in^2) of surface at reflux temperature for 2 hr on a 0.071 cm (0.028 in) thick sample. (Optionally, maximum net residue soluble in chloroform shall not exceed 0.00020 mg/cm^2 (0.0013 mg/in^2) of surface.).	0.002 mg/cm^2 (0.01 mg/in^2) of surface at 66 °C (150 °F) for 2 hr on a 0.071 cm (0.028 in) thick sample. (Optionally, maximum net residue soluble in chloroform shall not exceed 0.00040 mg/cm^2 (0.0025 mg/in^2) of surface.)
3. Styrene block polymers with 1,3-butadiene, hydrogenated; for use as articles or as components of articles that contact food of Types I, II, IV-B, VI, VII-B, and VIII identified in Table 1 in § 176.170(c) of this chapter.	16,000	do	−50 °C (−58 °F) to −30 °C (−22 °F) and 92 °C (198 °F) to 98 °C (208 °F).	0.002 mg/cm^2 (0.01 mg/in^2) of surface at reflux temperature for 2 hr on a 0.071 cm (0.028 in) thick sample.	0.002 mg/cm^2 (0.01 mg/in^2) of surface at 66 °C (150 °F) for 2 hr on a 0.071 cm (0.028 in) thick sample.

(c) The analytical methods for determining whether styrene block polymers conform to the specifications prescribed in this section are as follows and are applicable to the finished polymer.

(1) *Molecular weight.* Molecular weight shall be determined by intrinsic viscosity (or other suitable method).

(2) *Glass transition points.* The glass transition points shall be determined by either of the following methods:

(i) ASTM method D2236-70 ("Standard Method of Test for Dynamic Mechanical Properties of Plastics by Means of Torsional Pendulum," which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) modified by using a forced resonant vibration instead of a fixed vibration and by using frequencies of 25 to 40 cycles per second instead of 0.1 to 10 cycles per second.

(ii) Direct reading viscoelastometric method titled "Direct Reading Viscoelastrometric Method for Determining Glass Transition Points of Styrene Block Polymers" (which is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), by which the glass transition points are determined in the tensile mode of deformation at a frequency of 35 hertz using a Rheovibron Model DDV-II (or equivalent) Direct Reading Viscoelastometer. Take maxima in the out-of-phase component of the complex modulus as the glass transition points. For block polymers of low styrene content or for simple block polymers, the polymer may be treated with 0.3 part per hundred dicumyl peroxide and cured for 30 minutes at 153° C to accentuate the upper transition point.

(3) *Maximum extractable fractions in distilled water and 50 percent ethanol and the maximum net residue solubles in chloroform.* The maximum extractable fractions in distilled water and 50 percent ethanol, and the maximum net residue solubles in chloroform, shall be determined in accordance with § 176.170(d)(3) of this chapter using a sandwich form of the finished copolymer of the specified thickness and for the time and temperature specified in paragraph (b) of this section.

(d) The provisions of this section are not applicable to butadiene-styrene copolymers listed in other sections of this subpart.

(e) The provisions of this section are not applicable to styrene block polymers with 1,3-butadiene listed in § 175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 43621, Aug. 30, 1977; 47 FR 11844, Mar. 19, 1982; 51 FR 16828, May 7, 1986]

§ 177.1820 Styrene-maleic anhydride copolymers.

Styrene-maleic anhydride copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene-maleic anhydride copolymers are those produced by the polymerization of styrene and maleic anhydride so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(b) Specifications:

Styrene-maleic copolymers	Molecular weight (minimum number average)	Residual styrene monomer	Residual maleic anhydride monomer	Maximum extractable fraction in distilled water at specified temperatures, times, and particle size	Maximum extractable fraction in *n*-heptane at specified temperatures, times, and particle size
1. Styrene-maleic anhydride copolymers containing not more than 15 pct maleic anhydride units by weight; for use as articles or as components of articles that contact food of Types I, II, III, IV-A, IV-B, V, VI-B (except carbonated beverages), VII-A, VII-B, VIII, and IX identified in Table 1 in § 176.170(c) of this chapter under conditions of use B, C, D, E, F, G, and H described in Table 2 in § 176.170(c) of this chapter	70,000	0.3 weight percent.	0.1 weight percent.	0.006 weight percent at reflux temperature for 1 hr utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20	0.02 weight percent at 73° F for 2 hr utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20

Styrene-maleic copolymers	Molecular weight (minimum number average)	Residual styrene monomer	Residual maleic anhydride monomer	Maximum extractable fraction in distilled water at specified temperatures, times, and particle size	Maximum extractable fraction in *n*-heptane at specified temperatures, times, and particle size
2. Styrene-maleic anhydride copolymer modified with butadiene, (CAS Reg. No. 27288-99-9) containing not more than 15 percent maleic anhydride units by weight and not more than 20 percent styrene-butadiene and/or butadiene rubber units by weight, for use (except carbonated beverage bottles) as articles or as components of articles that contact food of Types I, II, III, IV-A, IV-B, V, VI, VII-A, VII-B, VIII, and IX identified in Table I in § 176.170(c) of this chapter under conditions of use B, C, D, E, F, G, and H described in Table 2 in § 176.170(c) of this chapter.	....	0.3	0.1	0.015 weight percent at reflux temperature for 1 hour utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.	1.0 weight percent at 23° C (73° F) for 2 hours utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.

(c) The analytical methods for determining conformance with specifications for styrene-maleic anhydride copolymers prescribed in this section are as follows:

(1) *Molecular weight.* Molecular weight shall be determined by membrane osmometry.

(2) *Residual styrene monomer content.* Residual styrene monomer content shall be determined by the method described in § 177.1640(d).

(3) *Residual maleic anhydride monomer content.* Residual maleic anhydride monomer content shall be determined by a gas chromatographic method titled "Determination of Residual Maleic Anhydride in Polymers by Gas Chromatography," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) The provisions of this section are not applicable to styrene-maleic anhydride copolymers listed in other sections of this subpart.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11844, Mar. 19, 1982; 47 FR 14698, Apr. 6, 1982]

§ 177.1830 Styrene-methyl methacrylate copolymers.

Styrene-methyl methacrylate copolymers identified in this section may be safely used as components of plastic articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, styrene-methyl methacrylate copolymers consist of basic copolymers produced by the copolymerization of styrene and methyl methacrylate such that the finished basic copolymers contain more than 50 weight percent of polymer units derived from styrene.

(b) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields extractives not to exceed the following when tested by the methods prescribed in § 177.1010(c);

(1) Total nonvolatile extractives not to exceed 0.3 milligram per square inch of surface tested.

(2) Potassium permanganate oxidizable distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.15.

(3) Ultraviolet-absorbing distilled water and 8 and 50 percent alcohol ex-

tractives not to exceed an absorbance of 0.30.

(4) Ultraviolet-absorbing *n*-heptane extractives not to exceed an absorbance of 0.40.

§ 177.1850 Textryls.

Textryls identified in this section may be safely used as articles or components of articles, intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food, subject to the provisions of this section.

(a) Textryls are nonwoven sheets prepared from natural or synthetic fibers, bonded with fibryl (Fibryl consists of a polymeric resin in fibrous form commingled with fiber to facilitate sheet formation and subsequently heat cured to fuse the fibryl and effect bonding).

(b) Textryls are prepared from the fibers, fibryls, and adjuvants identified in paragraph (c) of this section, and subject to limitations prescribed in that paragraph, provided that any substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specifications in such regulation for that substance as a component of polymeric resins used as food contact surfaces.

(c) The fibers, fibryls, and adjuvants permitted are as follows:

Substances	Limitations
(1) Fibers prepared from polyethylene terephthalate resins	Conforming with § 177.1630.
(2) Fibryls prepared from vinyl chloride-vinyl acetate copolymer.	As the basic polymer.
(3) Adjuvant substance, dimethylformamide	As a solvent in the preparation of fibryl.

(d) Textryls meeting the conditions of test prescribed in paragraph (d)(1) of this section are used as prescribed in paragraph (d)(2) of this section.

(1) *Conditions of test.* Textryls, when extracted with distilled water at reflux temperature for 1 hour, yield total extractives not to exceed 1 percent.

(2) *Uses.* Textryls are used for packaging or holding food at ordinary temperatures and in the brewing of hot beverages.

§ 177.1900 Urea-formaldehyde resins in molded articles.

Urea-formaldehyde resins may be safely used as the food-contact surface of molded articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, urea-formaldehyde resins are those produced when 1 mole of urea is made to react with not more than 2 moles of formaldehyde in water solution.

(b) The resins may be mixed with refined wood pulp and the mixture may contain other optional adjuvant substances which may include the following:

List of substances	Limitations
Hexamethylenetetramine	For use only as polymerization-control agent.
Tetrachlorophthalic acid anhydride.	Do.
Zinc stearate	For use as lubricant.

(c) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 175.300(d) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in § 175.300(e) of this chapter.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

§ 177.1950 Vinyl chloride-ethylene copolymers.

The vinyl chloride-ethylene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for contact with food, under conditions of use D, E, F, or G described in Table 2 of § 176.170 (c) of this chapter, subject to the provisions of this section.

(a) For the purpose of this section, vinyl chloride-ethylene copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and ethylene such that the finished basic copolymers meet the specifications and extractives limitations prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(b) The basic vinyl chloride-ethylene copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. The optional adjuvant substances required in the production of the basic vinyl chloride-ethylene copolymers may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) The vinyl chloride-ethylene basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is in the range of 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Intrinsic viscosity in cyclohexanone at 30° C is not less than 0.50 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.10 weight-percent when extracted with *n*-heptane at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150° F for 2 hours.

(iii) Total extractives obtained by extracting with water at 150° F for 2 hours contain no more than 0.5 milligram of vinyl chloride-ethylene copolymer per 100 grams of sample tested as determined from the organic chlorine content. The organic chlorine content is determined as described in paragraph (d)(3) of this section.

(d) Analytical methods: The analytical methods for determining whether vinyl chloride-ethylene basic copolymers conform to the extractives limitations prescribed in paragraph (c) of this section are as follows and are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and 80 percent will pass through a U.S. Standard Sieve No. 80:

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* All determinations shall be done in duplicate using duplicate blanks. Approximately 400 grams of sample (accurately weighed) shall be placed in a 2-liter Erlenmeyer flask. Add 1,200 milliliters of solvent and cover the flask with aluminum foil. The covered flask and contents are suspended in a thermostated bath and are kept, with continual shaking at 150° F for 2 hours. The solution is then filtered through a No. 42 Whatman filter paper, and the filtrate is collected in a graduated cylinder. The total amount of filtrate (without washing) is measured and called *A* milliliters. The filtrate is transferred to a Pyrex (or equivalent) beaker and evaporated on a steam bath under a stream of nitrogen to a small volume (approximately 50-60 milliliters). The concentrated filtrate is then quantitatively transferred to a tared 100-milliliter Pyrex beaker using small, fresh portions of solvent and a rubber policeman to effect the transfer. The concentrated filtrate is evaporated almost to dryness on a hotplate under

nitrogen, and is then transferred to a drying oven at 230° F in the case of the aqueous extract or to a vacuum oven at 150° F in the case of the heptane extract. In the case of the aqueous extract, the evaporation to constant weight is completed in 15 minutes at 230° F; and in the case of heptane extract, it is overnight under vacuum at 150° F. The residue is weighed and corrected for the solvent blank. Calculation:

$$\frac{\text{Grams of corrected residue}}{\text{Grams of sample}} \times \frac{1{,}200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100$$

=Total extractives expressed as percent by weight of sample.

(3) *Vinyl chloride-ethylene copolymer content of aqueous extract*—(i) *Principle.* The vinyl chloride-ethylene copolymer content of the aqueous extract can be determined by determining the organic chlorine content and calculating the amount of copolymer equivalent to the organic chlorine content.

(ii) *Total organic chlorine content.* A weighed sample of approximately 400 grams is extracted with 1,200 milliliters of water at 150° F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as described in paragraph (d)(2) of this section.

(*a*) A slurry of Amberlite IRA-400, or equivalent, is made with distilled water in a 150-milliliter beaker. The slurry is added to a chromatographic column until it is filled to about half its length. This should give a volume of resin of 15-25 milliliters. The liquid must not be allowed to drain below the top of the packed column.

(*b*) The column is regenerated to the basic (OH) form by slowly passing through it (10-15 milliliters per minute) 10 grams of sodium hydroxide dissolved in 200 milliliters of water. The column is washed with distilled water until the effluent is neutral to phenolphthalein. One drop of methyl red indicator is added to the *A* milliliters of filtered aqueous extract and, if on the basic side (yellow), nitric acid is added drop by drop until the solution turns pink.

(*c*) The extract is deionized by passing it through the exchange column at a rate of 10-15 milliliters per minute. The column is washed with 200 milliliters of distilled water. The deionized extract and washings are collected in a 1,500-milliliter beaker. The solution is evaporated carefully on a steam plate to a volume of approximately 50 milliliters and then transferred quantitatively, a little at a time, to a clean 22-milliliter Parr cup, also on the steam plate. The solution is evaporated to dryness. Next 0.25 gram of sucrose and 0.5 gram of benzoic acid are added to the cup. One scoop (approximately 15 grams) of sodium peroxide is then added to the cup. The bomb is assembled and ignition is conducted in the usual fashion.

(*d*) After the bomb has cooled, it is rinsed thoroughly with distilled water and disassembled. The top of the bomb is rinsed into a 250-milliliter beaker with distilled water. The beaker is placed on the steam plate. The bomb cup is placed in the beaker and carefully tipped over to allow the water to leach out the combustion mixture. After the bubbling has stopped, the cup is removed from the beaker and rinsed thoroughly. The solution is cooled to room temperature and cautiously neutralized with concentrated nitric acid by slowly pouring the acid down a stirring rod until the bubbling ceases. The solution is cooled and an equal volume of acetone is added.

(*e*) The solution is titrated with 0.005 *N* silver nitrate using standard potentiometric titration techniques with a silver electrode as indicator and a potassium nitrate modified calomel electrode as a reference electrode. An expanded scale recording titrimeter. Metrohm Potentiograph 2336 or equivalent, should be used; a complete blank must be run in duplicate.

(iii) *Calculations.*

Milligrams of aqueous extracted copolymer per 100-gram sample =

$$\frac{T \times F \times 64.3}{\text{Weight of sample in grams}} \times 100$$

where:

T = Milliliters of silver nitrate (sample minus blank) × normality of silver nitrate.
F = 1,200/A (as defined above)

(e) The vinyl chloride-ethylene copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) The provisions of this section are not applicable to vinyl chloride-ethylene copolymers used as provided in §§ 175.105 and 176.180 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1960 Vinyl chloride-hexene-1 copolymers.

The vinyl chloride-hexene-1 copolymers identified in paragraph (a) of this section or as components of articles intended for use in contact with food, under conditions of use D, E, F, or G described in Table 2 of § 176.170(c) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinyl chloride-hexene-1 copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and hexene-1 such that the finished copolymers contain not more than 3 mole-percent of polymer units derived from hexene-1 and meet the specifications and extractives limitations prescribed in paragraph (b) of this section. The copolymers may optionally contain hydroxypropyl methylcellulose and trichloroethylene used as a suspending agent and chain transfer agent, respectively, in their production.

(b) *Specifications and limitations.* The vinyl chloride-hexene-1 basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Inherent viscosity in cyclohexanone at 30° C is not less than 0.59 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods prescribed in § 177.1970(d).

(i) Total extractives do not exceed 0.01 weight percent when extracted with water at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.30 weight percent when extracted with *n*-heptane at 150° F for 2 hours.

(c) *Other specifications and limitations.* The vinyl chloride-hexene-1 copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1970 Vinyl chloride-lauryl vinyl ether copolymers.

The vinyl chloride-lauryl vinyl ether copolymers identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinyl chloride-lauryl vinyl ether copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and lauryl vinyl ether such that the finished copolymers contain not more than 3 weight-percent of polymer units derived from lauryl vinyl ether and meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic vinyl chloride-lauryl vinyl ether copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications and limitations.* The vinyl chloride-lauryl vinyl ether basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Inherent viscosity in cylcohexanone at 30° C is not less than 0.60 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Extractives limitations.* The following extractives limitations are determined by the method described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.60 weight-percent when extracted with *n*-heptane at 150° F for 2 hours.

(d) *Analytical methods.* The analytical methods for determining total extractives are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and such that not more than 10 percent will pass through a U.S. Standard Sieve No. 200.

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* Place an accurately weighed sample of suitable size in a clean borosilicate flask, and for each gram of sample add 3 milliliters of solvent previously heated to 150°F. Maintain the temperature of the contents of the flask at 150° F for 2 hours using a hot plate while also maintaining gentle mechanical agitation. Filter the contents of the flask rapidly through No. 42 Whatman filter paper with the aid of suction. Transfer the filtrate to flat glass dishes that are warmed on a hot plate and evaporate the solvent with the aid of a stream of filtered air. When the volume of the filtrate has been reduced to 10 to 15 milliliters, transfer the filtrate to tared 50-milliliter borosilicate glass beakers and complete evaporation to a constant weight in a 140° F vacuum oven. Carry out a corresponding blank determination with each solvent. Determine the weight of the residue corrected for the solvent blank and calculate the result as percent of the initial weight of the resin sample taken for analysis.

(e) *Other specifications and limitations.* The vinyl chloride-lauryl vinyl ether copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1980 Vinyl chloride-propylene copolymers.

The vinyl chloride-propylene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for contact with food, subject to the provisions of this section.

(a) For the purpose of this section, vinyl chloride-propylene copolymers consist of basic copolymers produced by the copolymezation of vinyl chloride and propylene such that the finished basic copolymers meet the specifications and extractives limitations prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(b) The basic vinyl chloride-propylene copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. The optional adjuvant substances required in the production of the basic vinyl chloride-propylene copolymers may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) The vinyl chloride-propylene basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is in the range of 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Intrinsic viscosity in cyclohexanone at 30° C is not less than 0.50 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.10 weight-percent when extracted with *n*-heptane at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150° F for 2 hours.

(iii) Total extractives obtained by extracting with water at 150° F for 2 hours contain no more than 0.17 milligram of vinyl chloride-propylene copolymer per 100 grams of sample tested as determined from the organic chlorine content. For the purpose of this section, the organic chlorine content is the difference between the total chlorine and ionic chlorine contents determined as described in paragraph (d) of this section.

(d) Analytical methods: The analytical methods for determining whether vinyl chloride-propylene basic copolymers conform to the extractives limitations prescribed in paragraph (c) of this section are as follows and are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and 80 percent will pass through a U.S. Standard Sieve No. 80:

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* All determinations shall be done in duplicate using duplicate blanks. Approximately 400 grams of sample (accurately weighed) shall be placed in a 2-liter Erlenmeyer flask. Add 1,200 milliliters of solvent and cover the flask with aluminum foil. The covered flask and contents are suspended in a thermostated bath and are kept, with continual shaking, at 150° F for 2 hours. The solution is then filtered through a No. 42 Whatman filter paper, and the filtrate is collected in a graduated cylinder. The total amount of filtrate (without washing) is measured and called *A* milliliters. The filtrate is transferred to a Pyrex (or equivalent) beaker and evaporated on a steam bath under a stream of nitrogen to a small volume (ap-

proximately 50-60 milliliters). The concentrated filtrate is then quantitatively transferred to a tared 100-milliliter Pyrex beaker using small, fresh portions of solvent and a rubber policeman to effect the transfer. The concentrated filtrate is evaporated almost to dryness on a hotplate under nitrogen, and is then transferred to a drying oven at 230° F in the case of the aqueous extract or to a vacuum oven at 150° F in the case of the heptane extract. In the case of the aqueous extract the evaporation to constant weight is completed in 15 minutes at 230° F; and in the case of heptane extract, it is overnight under vacuum at 150° F. The residue is weighed and corrected for the solvent blank. Calculation:

$$\frac{\text{Grams of corrected residue}}{\text{Grams of sample}} \times \frac{\text{1,200 milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100$$

= Total extractives expressed as percent by weight of sample.

(3) *Vinyl chloride-propylene copolymer content of aqueous extract*—(i) *Principle.* The vinyl chloride-propylene copolymer content of the aqueous extract can be determined by determining the organic chlorine content and calculating the amount of copolymer equivalent to the organic chlorine content. The organic chlorine content is the difference between the total chlorine content and the ionic chlorine content.

(ii) *Total chlorine content.* A weighed sample is extracted with water at 150° F for 2 hours, filtered, and the volume of filtrate is measured (A milliliters) as described in paragraph (d)(2) of this section. Two drops of 50 percent by weight sodium hydroxide solution are added to prevent loss of chloride from ammonium chloride, if present, and the solution is evaporated to approximately 15 milliliters. The concentrated filtrate is quantitatively transferred to a 22-milliliter Parr bomb fusion cup and gently evaporated to dryness. To the contents of the cup are added 3.5 grams of granular sodium peroxide, 0.1 gram of powdered starch, and 0.02 gram potassium nitrate; and the contents are mixed thoroughly. The bomb is assembled, water is added to the recess at the top of the bomb and ignition is conducted in the usual fashion using a Meeker burner. The heating is continued for 1 minute after the water at the top has evaporated. The bomb is quenched in water, rinsed with distilled water, and placed in a 400-milliliter beaker. The bomb cover is rinsed with water, catching the washings in the same 400-milliliter beaker. The bomb is covered with distilled water and a watch glass and heated until the melt has dissolved. The bomb is removed, rinsed, catching the rinsings in the beaker, and the solution is acidified with concentrated nitric acid using methyl purple as an indicator. The beaker is covered with a watch glass, and the contents are boiled gently for 10-15 minutes. After cooling to room temperature the solution is made slightly alkaline with 50 percent by weight sodium hydroxide solution, then acidified with dilute (1:5) nitric acid. Then 1.5 milliliters of 2 N nitric acid per 100 milliliters of solution is added and the solution is titrated with 0.005 N silver nitrate to the equivalence potential end point using an expanded scale pH meter (Beckman Model 76, or equivalent). A complete blank must be run in duplicate. Calculation:

$$\begin{matrix}\text{Grams of sample}\\(B-C)\end{matrix} \times \frac{\text{1,200 milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100$$

= Milliequivalents of total chlorine in aqueous extract of 100 grams of sample.

where:

A = volume of filtrate obtained in extraction.

B = milliliters of silver nitrate solution used in sample titration × normality of silver nitrate solution.

C = milliliters of silver nitrate solution used in blank titration × normality of silver nitrate solution.

(iii) *Ionic chlorine content.* A weighed sample is extracted with water at 150° F for 2 hours, filtered, and the volume of filtrate is measured (A milliliters) as in paragraph (d)(2) of this section. Two drops of 50 percent by weight sodium hydroxide solution are added and the solution is evaporated to approximately 150 milliliters.

The solution is quantitatively transferred to a 250-milliliter beaker, methyl purple indicator is added, and the solution is neutralized with 0.1 *N* nitric acid. For each 100 milliliters of solution is added 1.5 milliliters of 2 *N* nitric acid. The solution is titrated with 0.005 *N* silver nitrate to the equivalence potential end point, using the expanded scale pH meter described in paragraph (d)(3)(ii) of this section. A complete blank must be run in duplicate. Calculation:

$$\frac{D\text{-}E}{\text{Grams of sample}} \times \frac{1{,}200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100$$

= Milliequivalents of ionic chlorine in aqueous extract of 100 grams of sample.

where:

A = volume of filtrate obtained in extraction.

D = milliliters of silver nitrate solution used in sample titration × normality of silver nitrate solution.

E = milliliters of silver nitrate solution used in blank titration × normality of silver nitrate solution.

(iv) *Organic chlorine content and vinyl chloride-propylene copolymer content of aqueous extract.* The organic chlorine content and the vinyl chloride propylene copolymer content of the aqueous extract is calculated as follows:

(*a*) *Organic chlorine content.* Milliequivalents of organic chlorine in aqueous extract of 100 grams of sample equal milliequivalents of total chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(ii) of this section) minus milliequivalents of ionic chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(iii) of this section).

(*b*) *Vinyl chloride-propylene copolymer content.* Milligrams of vinyl chloride-propylene copolymer in aqueous extract of 100 grams of sample equal milliequivalents of organic chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(iv) (*a*) of this section) multiplied by 84.5.

NOTE: The conversion factor, 84.5, is derived from the equivalent weight of chlorine divided by the chlorine content of the heptane extractable fraction.)

(e) The vinyl chloride-propylene copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) The provisions of this section are not applicable to vinyl chloride-propylene copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984]

§ 177.1990 Vinylidene chloride/methyl acrylate copolymers.

The vinylidene chloride/methyl acrylate copolymers (CAS Reg. No. 25038-72-6) identified in paragraph (a) of this section may be safely used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinylidene chloride/methyl acrylate copolymers consist of basic copolymers produced by the copolymerization of vinylidene chloride and methyl acrylate such that the copolymers contain not more than 15 weight-percent of polymer units derived from methyl acrylate.

(b) *Optional adjuvant substances.* The basic vinylidene chloride/methyl acrylate copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications.* (1) The methyl acrylate content is determined by an infrared spectrophotometric method titled "Determination of Copolymer Ratio in Vinylidene Chloride/Methyl Acrylate Copolymers," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The weight average molecular weight of the copolymer is not less than 50,000 when determined by gel permeation chromatography using tetrahydrofuran as the solvent. The gel permeation chromatograph is calibrated with polystyrene standards. The basic gel permeation chromatographic method is described in ANSI/ASTM D3536-76, "Standard Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by Liquid Exclusion Chromatography (Gel Permeation Chromatography-GPC)," which is incorporated by reference. Copies are available from University Microfilms International, 300 North Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Residual vinylidene chloride and residual methyl acrylate in the copolymer in the form in which it will contact food (unsupported film, barrier layer, or as a copolymer for blending) will not exceed 10 parts per million and 5 parts per million, respectively, as determined by a gas chromatographic method titled "Determination of Residual Vinylidene Chloride and Methyl Acrylate in Vinylidene Chloride/Methyl Acrylate Copolymer Resins and Films," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington DC 20408.

(d) *Extractives limitations.* The basic copolymer resin in the form of granules that will pass through a U.S. Standard Sieve No. 45 (350 microns) shall meet the following extractives limitations:

(1) 10-gram samples of the resin, when extracted separately with 100 milliliters of distilled water at 121° C (250° F) for 2 hours, and 100 milliliters of *n*-heptane at 66° C (150° F) for 2 hours, shall yield total nonvolatile extractives not to exceed 0.5 percent by weight of the resin.

(2) The basic copolymer in the form of film when extracted separately with distilled water at 121° C (250° F) for 2 hours shall yield total nonvolatile extractives not to exceed 0.047 milligram per square centimeter (0.3 milligram per square inch).

(e) *Conditions of use.* The copolymers may be safely used as articles or components of articles intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food, including processing of packaged food at retorting temperature, 121° C (250° F).

(f) *Other specifications and limitations.* The vinylidene chloride-methyl acrylate copolymers identified in and complying with this section, when used as components of the food contact surface of any article that is subject to a regulation in Parts 174 through 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

[48 FR 38605, Aug. 25, 1983; 48 FR 50077, Oct. 31, 1983]

§ 177.2000 Vinylidene chloride/methyl acrylate/methyl methacrylate polymers.

The vinylidene chloride/methyl acrylate/methyl methacrylate polymers (CAS Reg. No. 34364-83-5) identified in paragraph (a) of this section may be safely used as articles or as a component of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, vinylidene chloride/methyl acrylate/methyl methacrylate polymers consist of basic polymers produced by the copolymerization of vinylidene chloride/methyl acrylate/methyl methacrylate such that the basic polymers or the finished food-contact articles meet the specifications prescribed in paragraph (d) of this section.

(b) *Optional adjuvant substances.* The basic vinylidene chloride/methyl acrylate/methyl methacrylate polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction of approval.

(c) *Conditions of use.* The polymers may be safely used as articles or as components of articles intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food, including processing of packaged food at temperatures up to 121° C (250° F).

(d) *Specifications and limitations.* The vinylidene chloride/methyl acrylate/methyl methacrylate basic polymers and/or finished food-contact articles meet the following specifications and limitations:

(1)(i) The basic vinylidene chloride/methyl acrylate/methyl methacrylate polymers contain not more than 2 weight percent of polymer units derived from methyl acrylate monomer and not more than 6 weight percent of polymer units derived from methyl methacrylate monomer.

(ii) The basic polymers are limited to a thickness of not more than 0.005 centimeter (0.002 inches).

(2) The weight average molecular weight of the basic polymer is not less than 100,000 when determined by gel permeation chromatography using tetrahydrofuran as the solvent. The gel permeation chromatography is calibrated with polystyrene standards. The basic gel permeation chromatographic method is described in ANSI/ASTM D3536-76, which is incorporated by reference. Copies are available from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) The basic polymer or food-contact article described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields net chloroform-soluble extractives in each extracting solvent not to exceed .08 milligram per square centimeter (0.5 milligram per square inch) of food-contact surface when tested by the methods described in § 176.170(d). If the finished food-contact article is itself the subject of a regulation in Parts 174 through 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by the regulation.

[49 FR 29578, July 23, 1984]

Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

§ 177.2210 Ethylene polymer, chlorosulfonated.

Ethylene polymer, chlorosulfonated as identified in this section may be safely used as an article or component of articles intended for use in contact with food, subject to the provisions of this section.

(a) Ethylene polymer, chlorosulfonated is produced by chlorosulfonation of a carbon tetrachloride solution of polyethylene with chlorine and sulfuryl chloride.

(b) Ethylene polymer, chlorosulfonated shall meet the following specifications:

(1) Chlorine not to exceed 25 percent by weight.

(2) Sulfur not to exceed 1.15 percent by weight.

(3) Molecular weight is in the range of 95,000 to 125,000.

Methods for the specifications in this paragraph (b), titled "Chlorine and Bromine—Coulometric Titration Method by Aminco Chloridometer," "Hypolon" Synthetic Rubber—Determination of Sulfur by Parr Bomb," and ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," are incorporated by reference. Copies of the ASTM method may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103. Copies of the other two methods are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Copies of all three methods may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The additive is used as the article, or a component of articles, intended for use as liners and covers for reservoirs intended for the storage of water for drinking purposes.

(d) Substances permitted by § 177.2600 may be employed in the preparation of ethylene polymers, chlorosulfonated, subject to any limitations prescribed therein.

(e) The finished ethylene copolymers, chlorosulfonated shall conform to § 177.2600(e) and (g).

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984]

§ 177.2250 Filters, microporous polymeric.

Microporous polymeric filters identified in paragraph (a) of this section may be safely used, subject to the provisions of this section, to remove particles of insoluble matter in producing, manufacturing, processing, and preparing bulk quantities of liquid food.

(a) Microporous polymeric filters consist of a suitably permeable, continuous, polymeric matrix of polyvinyl chloride, vinyl chloride-propylene, or vinyl chloride-vinyl acetate, in which finely divided silicon dioxide is embedded. Cyclohexanone may be used as a solvent in the production of the filters.

(b) Any substance employed in the production of microporous polymeric filters that is the subject of a regulation in Parts 170 through 189 of this chapter must conform with any specification in such regulation.

(c) Cyclohexanone when used as a solvent in the production of the filters shall not exceed 0.35 percent by weight of the microporous polymeric filters.

(d) The microporous polymeric filters may be colored by the pigments and colorants identified in § 175.300(b)(3)(xxvi) of this chapter.

(e) The temperature of food being processed through the microporous polymeric filters shall not exceed 180° F.

(f) The microporous polymeric filters shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(g) To assure safe use of the microporous polymeric filters, the label or labeling shall include adequate directions for a pre-use treatment, consisting of washing with a minimum of 2 gallons of potable water at a temperature of 180° F for each square foot of filter, prior to the filter's first use in contact with food.

§ 177.2260 Filters, resin-bonded.

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials, together with adjuvant substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that is the subject of a regulation in Parts

174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of resin-bonded filters include the following, subject to any limitations provided:

List of Substances and Limitations

(1) *Fibers:*
  Cellulose pulp.
  Cotton.
  Nylon. (From nylon resins complying with the provisions of applicable regulations in Subchapter B of this chapter.
  Polyethylene terephthalate complying in composition with the provisions of § 177.1630; for use in inline filtration only as provided for in paragraphs (e) and (f) of this section.
  Rayon (viscose).
(2) *Substances employed in fiber finishing:*
  BHT.
  Butyl (or isobutyl) palmitate or stearate.
  2,5-Di-*tert*-butyl hydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.
  Dimethylpolysiloxane.
  4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.
  Fatty acid (C_{10}-C_{18}) diethanolamide condensates.
  Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:
    Aluminum.
    Ammonium.
    Calcium.
    Magnesium.
    Potassium.
    Sodium.
    Triethanolamine.
  Fatty acid (C_{10}-C_{18}) mono- and diesters of polyoxyethylene glycol (molecular weight 400-3,000).
  Methyl esters of fatty acids (C_{10}-C_{18}).
  Mineral oil.
  Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740 (b) of this chapter.
  Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 10 percent by weight of the lubricant formulations.
  Riceuran oil.
  Titanium dioxide.
(3) *Resins:*
  Acrylic polymers produced by polymerizing ethyl acrylate alone or with one or more of the monomers: Acrylic acid, acrylonitrile, *N*-methylolacrylamide, and styrene. The finished copolymers shall contain at least 70 weight percent of polymer units derived from ethyl acrylate, no more than 2 weight percent of total polymer units derived from acrylic acid, no more than 10 weight percent of total polymer units derived from acrylonitrile, no more than 2 weight percent of total polymer units derived from *N*-methylolacrylamide, and no more than 25 weight percent of total polymer units derived from styrene. For use only as provided in paragraph (m) of this section.
  Melamine-formaldehyde.
  Melamine-formaldehyde chemically modified with one or more of the amine catalysts identified in § 175.300(b)(3)(xiii) of this chapter.
  Melamine-formaldehyde chemically modified with methyl alcohol.
  Melamine-formaldehyde chemically modified with urea; for use only as provided for in paragraphs (e), (f), (g), (h), and (i) of this section.
  Phenol-formaldehyde resins.
  Polyvinyl alcohol.
  Polyvinyl alcohol with the copolymer of acrylic acid-allyl sucrose.
  Polyvinyl alcohol with melamine formaldehyde.
  Polyvinyl acetate with melamine formaldehyde.
  p-Toluenesulfonamide-formaldehyde chemically modified with one or more of the amine catalysts identified in § 175.300 (b)(3)(xiii) of this chapter.
(4) *Adjuvant substances:*
  Dimethyl polysiloxane with methylcellulose and sorbic acid (as an antifoaming agent).
  Phosphoric acid.
(5) *Colorants:*
  Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160), not to exceed 0.1 percent in thermoplastic adhesives fabricated from components complying with §§ 177.1350 and 177.1520 for use in resin-bonded filters.

(e) Resin-bonded filters conforming with the specifications of paragraph (e) (1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 100°F for 2 hours, yields total extractives not to exceed 2.8 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk or potable water at operating temperatures not to exceed 100°F.

(f) Resin-bonded filters conforming with the specifications of paragraph (f) (1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 145°F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk or potable water at operating temperatures not to exceed 145°F.

(g) Resin-bonded filters conforming with the specifications of paragraph (g) (1) of this section are used as provided in paragraph (g)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.5 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter edible oils.

(h) Resin-bonded filters conforming with the specifications of paragraph (h) (1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 212°F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk, coffee, tea, and potable water at temperatures not to exceed 212°F.

(i) Resin-bonded filters conforming with the specifications of paragraph (i) (1) of this section are used as provided in paragraph (i)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH above 5.0.

(j) Resin-bonded filters conforming with the specifications of paragraph (j) (1) of this section are used as provided in paragraph (j)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 5 percent (by weight) acetic acid for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH of 5.0 or below.

(k) Resin-bonded filters conforming with the specifications of paragraph (k) (1) of this section are used as provided in paragraph (k)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 8 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of alcoholic beverages containing not more than 8 percent alcohol.

(l) Resin-bonded filters conforming with the specifications of paragraph (l) (1) of this section are used as provided in paragraph (l)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 50 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of alcoholic beverages containing more than 8 percent alcohol.

(m) Resin-bonded filters fabricated from acrylic polymers as provided in paragraph (d)(3) of this section together with other substances as provided in paragraph (d), (1), (2), and (4) of this section may be used as follows:

(1) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 100°F, provided that the finished filter when exposed to distilled water at 100°F for 2 hours yields total extractives not to exceed 1 percent by weight of the filter.

(2) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 145°F, provided that the finished filter when exposed to distilled water at 145°F for 2 hours yields total extractives not to exceed 1.2 percent by weight of the filter.

(n) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 177.2280 4,4′-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins.

4,4′-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The basic thermosetting epoxy resin is made by reacting 4,4′-isopropylidenediphenol with epichlorohydrin.

(b) The resin may contain one or more of the following optional substances provided the quantity used does not exceed that reasonably required to accomplish the intended effect:

Allyl glycidyl ether	As curing system additive
Di- and tri-glycidyl ester mixture resulting from the reaction of epichlorohydrin with mixed dimers and trimers of unsaturated C_{18} monobasic fatty acids derived from animal and vegetable fats and oils	As modifier at levels not to exceed equal parts by weight of the 4,4′-isopropylidenediphenol-epichlorohydrin basic resin and limited to use in contact with alcoholic beverages containing not more than 8 percent of alcohol
1,2-Epoxy-3-phenoxypropane	As curing system additive
Glyoxal	Do
4,4′-Isopropylidenediphenol	Do
4,4′-Methylenedianiline	Do
m-Phenylenediamine	Do
Tetrahydrophthalic anhydride	Do

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleansed prior to their first use in contact with food.

(d) The provisions of this section are not applicable to 4,4′-isopropylidenediphenol-epichlorohydrin resins listed in other sections of Parts 174, 175, 176, 177, 178 and 179 of this chapter.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984]

§ 177.2355 Mineral reinforced nylon resins.

Mineral reinforced nylon resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with nonacidic food (pH above 5.0) and at use temperatures not exceeding 212° F. in accordance with the following prescribed conditions:

(a) For the purpose of this section the mineral reinforced nylon resins consist of nylon 66, as identified in and complying with the specifications of § 177.1500, reinforced with up to 40 weight percent of calcium silicate and up to 0.5 weight percent 3-(triethoxysilyl) propylamine (Chemical Abstracts Service Registry No. 000919302) based on the weight of the calcium silicate.

(b) The mineral reinforced nylon resins may contain up to 0.2 percent by weight of titanium dioxide as an optional adjuvant substance.

(c) The mineral reinforced nylon resins with or without the optional substance described in paragraph (b) of this section, and in the form of ⅛-inch molded test bars, when extracted with the solvents, i.e., distilled water and 50 percent (by volume) ethyl alcohol in distilled water, at reflux temperature for 24 hours using a volume-to-surface ratio of 2 milliliters of solvent per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 5.0 milligrams per square inch of food-contact surface tested for each solvent.

(2) The ash after ignition of the extractives described in paragraph (c)(1) of this section, not to exceed 0.5 milligram per square inch of food-contact surface tested.

(d) In accordance with good manufacturing practice, finished articles containing the mineral reinforced nylon resins shall be thoroughly cleansed prior to their first use in contact with food.

[42 FR 54533, Oct. 7, 1977, as amended at 42 FR 61594, Dec. 6, 1977]

§ 177.2400 Perfluorocarbon cured elastomers.

Perfluorocarbon cured elastomers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with nonacid food (pH above 5.0), subject to the provisions of this section.

(a) *Identity.* (1) For the purpose of this section, perfluorocarbon cured elastomers are produced by terpolymerizing tetrafluorethylene (CAS Reg. No. 116-14-3), perfluoromethyl vinyl ether (CAS Reg. No. 1187-93-5), and perfluoro-2-phenoxypropyl vinyl ether (CAS Reg. No. 24520-19-2) and subsequent curing of the terpolymer (CAS Reg. No. 26658-70-8) using the cross-linking agent, phenol, 4,4′-[2,2,2-trifluoro-1-(trifluoromethyl) ethylidene] bis-,dipotassium salt (CAS Reg. No. 25088-69-1) and accelerator, 1,4,7,10,13,16-hexaoxacyclooctadecane (CAS Reg. No. 17455-13-9).

(2) The perfluorocarbon base polymer shall contain no less than 40 weight-percent of polymer units derived from tetrafluoroethylene, no less than 40 weight-percent of polymer units derived from perfluoromethyl vinyl ether and no more than 5 weight-percent polymer units derived from perfluoro-2-phenoxy-propyl vinyl ether.

(3) The composition limitations of the cured elastomer, calculated as parts per 100 parts of terpolymer, are as follows: Phenol, 4,4′-[2,2,2-trifluoro-1-(trifluoromethyl)-ethylidene] bis-,dipotassium salt—not to exceed 5 parts. 1,4,7,10,13,16-Hexaoxacyclooctadecane—not to exceed 5 parts.

(b) *Optional adjuvant substances.* The perfluorocarbon cured elastomer identified in paragraph (a) of this section may contain the following optional adjuvant substances, subject to any limitations cited on their use:

(1) Substances generally recognized as safe (GRAS) in food or food packaging.

(2) Substances used in accordance with a prior sanction.

(3) Substances authorized under applicable regulations in this part and in Parts 175 and 178 of this chapter and subject to any limitations prescribed therein.

(4) Substances identified in this paragraph (b)(4) subject to such limitations as are provided:

Substances	Limitations
Carbon black (channel process of furnace combustion process) (CAS Reg. No 1333-86-4)	Not to exceed 15 parts per 100 parts of the terpolymer.
Magnesium oxide (CAS Reg. No 1309-48-4)	Not to exceed 5 parts per 100 parts of the terpolymer.

(c) *Specifications*—(1) *Infrared identification.* Perfluorocarbon cured elastomers may be identified by the characteristic infrared spectra of the pyrolysate breakdown product that is obtained by heating and decomposing the elastomer using the method entitled "Qualitative Identification of Kalrez® by Infrared Examination of Pyrolysate." This method is incorporated by reference. Copies of the method are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Thermogravimetry.* Perfluorocarbon cured elastomers have a major decomposition peak occurring at 490 °±15 °C (914 °F). Less than 1.5 percent

of the elastomers will volatilize below 400 °C (752 °F) when run under nitrogen at a 10 °C or 18 °F per minute heating rate using a Du Pont Thermal Analyzer Model 1099 with Model 951 TGA unit or the equivalent.

(d) *Extractive limitations.* Articles fabricated from perfluorocarbon cured elastomers having a thickness of at least 1.0 millimeter (0.039 inch) when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, and *n*-heptane, shall meet the following extractability limits:

(1) Total extractives not to exceed 3.1 milligrams per square decimeter (0.2 milligrams per square inch).

(2) Fluoride extractives calculated as fluorine not to exceed 0.47 milligram per square decimeter (0.03 milligram per square inch).

(e) *Conditions of use.* In accordance with current good manufacturing practice, finished food contact articles containing the perfluorocarbon cured elastomers shall be thoroughly cleaned prior to their first use in contact with food.

[49 FR 43050, Oct. 26, 1984]

§ 177.2410 Phenolic resins in molded articles.

Phenolic resins identified in this section may be safely used as the food-contact surface of molded articles intended for repeated use in contact with nonacid food (pH above 5.0), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the phenolic resins are those produced when one or more of the phenols listed in paragraph (a)(1) of this section are made to react with one or more of the aldehydes listed in paragraph (a)(2) of this section, with or without aniline and/or anhydro-formaldehyde aniline (hexahydro-1, 3,5-triphenyl-s-triazine):

(1) *Phenols:*

p-tert-Amylphenol.
p-tert-Butylphenol.
o-, *m*-, and *p*-Cresol.
p-Octylphenol.
Phenol.
o- and *p*-Phenylethylphenol mixture produced when phenol is made to react with styrene in the presence of sulfuric acid catalyst.

(2) *Aldehydes:*

Acetaldehyde.
Formaldehyde.
Paraldehyde.

(b) Optional adjuvant substances employed in the production of the phenolic resins or added thereto to impart desired technical or physical properties include the following:

Asbestos fiber	
Barium hydroxide	For use as catalyst.
Calcium stearate	For use as lubricant.
Carbon black (channel process)	
Diatomaceous earth	
Glass fiber	
Hexamethylenetetramine	For use as curing agent.
Mica	
Oxalic acid	For use as catalyst.
Zinc stearate	For use as lubricant.

(c) The finished food-contact article, when extracted with distilled water at reflux temperature for 2 hours, using a volume-to-surface ratio of 2 milliliters of distilled water per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 0.15 milligram per square inch of food-contact surface.

(2) Extracted phenol not to exceed 0.005 milligram per square inch of food-contact surface.

(3) No extracted aniline when tested by a spectrophotometric method sensitive to 0.006 milligram of aniline per square inch of food-contact surface.

(d) In accordance with good manufacturing practice, finished molded articles containing the phenolic resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2420 Polyester resins, cross-linked.

Cross-linked polyester resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) The cross-linked polyester resins are produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols or epoxides listed in paragraph (a)(2) of this section, followed by copolymerization with one or more of the cross-linking agents listed in paragraph (a)(3) of this section:

(1) Acids:

Adipic.
Fatty acids, and dimers thereof, from natural sources.
Fumaric.
Isophthalic.
Maleic.
Methacrylic.
Orthophthalic.
Sebacic.
Terephthalic.
Trimellitic.

(2) Polyols and polyepoxides:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol.
Dipropylene glycol.
Ethylene glycol.
Glycerol.
4,4′ - Isopropylidenediphenol - epichlorohydrin.
Mannitol.
α-Methyl glucoside.
Pentaerythritol.
Polyoxypropylene ethers of 4,4′-isopropylide-nediphenol (containing an average of 2–7.5 moles of propylene oxide).
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.
2,2,4-Trimethyl-1,3-pentanediol.

(3) Cross-linking agents:

Butyl acrylate.
Butyl methacrylate.
Ethyl acrylate.
Ethylhexyl acrylate.
Methyl acrylate.
Methyl methacrylate.
Styrene.
Triglycidyl isocyanurate (CAS Reg. No. 2451-62-9), for use only in coatings contacting bulk quantities of dry food of the type identified in § 176.170(c) of this chapter, Table 1, under type VIII.
Vinyl toluene.

(b) Optional adjuvant substances employed to facilitate the production of the resins or added thereto to impart desired technical or physical properties include the following, provided that the quantity used does not exceed that reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations prescribed in this section:

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
1. Inhibitors:	Total not to exceed 0.08 percent.
Benzoquinone	0.01 percent.
tert-Butyl catechol	
TBHQ	
Di-*tert*-butyl hydroquinone	
Hydroquinone	
2. Accelerators:	Total not to exceed 1.5 percent.
Benzyl trimethyl ammonium chloride	0.05 percent.
Calcium naphthenate	
Cobalt naphthenate	
Copper naphthenate	
N, N-Diethylaniline	0.4 percent.
N, N-Dimethylaniline	Do.
Ethylene guanidine hydrochloride	0.05 percent.
3. Catalysts:	Total not to exceed 1.5 percent, except that methyl ethyl ketone peroxide may be used as the sole catalyst at levels not to exceed 2 percent.
Azo-bis-isobutyronitrile	
Benzoyl peroxide	
tert-Butyl perbenzoate	
Chlorbenzoyl peroxide	
Cumene hydroperoxide	
Dicumyl peroxide	
Lauroyl peroxide	
p-Menthane hydroperoxide	
Methyl ethyl ketone peroxide	
4. Solvents for inhibitors, accelerators, and catalysts:	
Butyl benzyl phthalate (containing not more than 1.0 percent by weight of dibenzyl phthalate).	
Dibutyl phthalate	
Diethylene glycol	As a solvent for benzyl trimethyl ammonium chloride or ethylene guanidine hydrochloride only.
Dimethyl phthalate	

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
Methyl alcohol	
Styrene	
Triphenyl phosphate	
5 Reinforcements:	
Asbestos	
Glass fiber	
Polyester fiber produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols listed in paragraph (a)(2) of this section	
6 Miscellaneous materials:	
Castor oil, hydrogenated	
α-Methylstyrene	
Polyethylene glycol 6000	
Silicon dioxide	
Wax, petroleum	Complying with § 178.3710 of this chapter

(c) The cross-linked polyester resins, with or without the optional substances described in paragraph (b) of this section, and in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of their intended use, as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall meet the following extractives limitations:

(1) Net chloroform-soluble extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is water or 8 or 50 percent alcohol.

(2) Total nonvolatile extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is heptane.

(d) In accordance with good manufacturing practice, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 37618, Aug. 19, 1983]

§ 177.2430 Polyether resins, chlorinated.

Chlorinated polyether resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The chlorinated polyether resins are produced by the catalytic polymerization of 3,3-bis(chloromethyl)-oxetane, and shall contain not more than 2 percent residual monomer.

(b) In accordance with good manufacturing practice, finished articles containing the chlorinated polyether resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2440 Polyethersulfone resins.

Polyethersulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyethersulfone resins are poly(oxy-*p*-phenylenesulfonyl-*p*-phenylene) resins (CAS Reg. No. 25667-42-9), which have a minimum number average molecular weight of 16,000, as determined by reduced viscosity in dimethyl formamide in accordance with ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) The basic resins identified in paragraph (a) of this section may contain optional adjuvant substances used in their production. These adjuvants may include substances described in § 174.5(d) of this chapter and the following:

List of substances	Limitations
Diphenylsulfone	Not to exceed 0.2 percent as residual solvent in the finished basic resin.
Dimethyl sulfoxide	Not to exceed 0.01 percent as residual solvent in the finished basic resin.

(c) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields net chloroform-soluble extractives in each extracting solvent not to exceed 0.02 milligram per square inch of food-contact surface: distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. (Note: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(d) In accordance with good manufacturing practice, finished food-contact articles containing the polyethersulfone resins shall be thoroughly cleansed before their first use in contact with food.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[44 FR 34493, June 15, 1979, as amended at 47 FR 38885, Sept. 3, 1982; 49 FR 10111, Mar. 19, 1984; 50 FR 47211, Nov. 15, 1985]

§ 177.2450 Polyamide-imide resins.

Polyamide-imide resins identified in paragraph (a) of this section may be safely used as components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) *Identity.* For the purposes of this section the polyamide-imide resins are derived from the condensation reaction of substantially equimolar parts of trimellitic anhydride and *p,p'*-diphenylmethane diisocyanate.

(b) *Specifications.* Polyamide-imide resins identified in paragraph (a) of this section shall conform to the following specifications:

(1) Nitrogen content: Not less than 7.80 weight percent and not more than 8.20 weight percent, as determined by the Dumas Nitrogen Determination as set forth in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 7.016-7.020, which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Solution viscosity: Not less than 1.200 as determined by a method titled "Solution Viscosity," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Residual monomers as determined by gas chromatography (the gas chromatographic method titled "Amide-Imide Polymer Analysis—Analysis of Monomer Content," is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), in the polyamide-imide resin, heat cured at 600° F for 15 minutes: *p,p'*-diphenylmethane diisocyanate, not more than 100 parts per million; trimellitic anhydride, not more than 500 parts per million.

(c) Extractive limitations are applicable to the polyamide-imide resin in the form of films of 1 mil uniform thickness after coating and heat-curing at 600° F for 15 minutes on stainless steel plates, each having such resin-coated surface area of 100 square inches. The cured-resin film coatings shall be extracted in accordance with the method described in

§ 176.170(d)(3) of this chapter, using a plurality of spaced, coated stainless steel plates, exposed to the respective food simulating solvents. The resin shall meet the following extractive limitations under the corresponding extraction conditions:

(1) Distilled water at 250° F for 2 hours: Not to exceed 0.01 milligram per square inch.

(2) Three percent acetic acid at 212° F for 2 hours: Not to exceed 0.05 milligram per square inch.

(3) Fifty percent ethyl alcohol at 160° F for 2 hours: Not to exceed 0.03 milligram per square inch.

(4) *n*-Heptane at 150° F for 2 hours: Not to exceed 0.05 milligram per square inch.

(d) In accordance with good manufacturing practice, those food contact articles, having as components the polyamide-imide resins identified in paragraph (a) of this section and intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11845, Mar. 19, 1982; 49 FR 10111, Mar. 19, 1984]

§ 177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins.

The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, poly(2,6-dimethyl-1,4-phenylene) oxide resins consist of basic resins produced by the oxidative coupling of 2,6-xylenol such that the finished basic resins meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic poly(2,6-dimethyl-1,4-phenylene) oxide resins may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations (expressed as percent by weight of finished basic resin)
Diethylamine	Not to exceed 0.16 percent as residual catalyst
Methyl alcohol	Not to exceed 0.02 percent as residual solvent
Toluene	Not to exceed 0.2 percent as residual solvent

(c) *Specifications and extractives limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide basic resins meet the following:

(1) *Specifications.* Intrinsic viscosity is not less then 0.40 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference, modified as follows. Copies of the incorporation by reference may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(i) *Solvent:* Chloroform, reagent grade containing 0.01 percent *tert*-butylcatechol.

(ii) *Resin sample:* Powdered resin obtained from production prior to molding or extrusion.

(iii) *Viscometer:* Cannno-Ubbelohde series 25 dilution viscometer (or equivalent).

(iv) *Calculation:* The calculation method used is that described in Appendix X.1.3 (ASTM method D1243-79, cited and incorporated by reference in paragraph (c)(1) of this section) with the reduced viscosity determined for three concentration levels (0.4, 0.2, and 0.1 gram per deciliter) and extrapolated to zero concentration for intrinisic viscosity. The following formula is used for determining reduced viscosity:

Reduced viscosity in terms of deciliters per gram =

$$\frac{t - t_0}{t_0 \times c}$$

Where:
t = Solution efflux time.
t_0 = Solvent efflux time.
c = Concentration of solution in terms of grams per deciliter.

(2) *Extractives limitations.* Total resin extracted not to exceed 0.02 weight-percent when extracted with *n*-heptane at 160°F for 2 hours as determined using 200 milliliters of reagent grade *n*-heptane which has been freshly distilled before use and 25 grams of poly (2,-6-dimethyl-1,4-phenylene) oxide resin. The resin as tested is in pellet form having a particle size such that 100 percent of the pellets will pass through a U.S. Standard Sieve No. 6 and 100 percent of the pellets will be held on a U.S. Standard Sieve No. 10.

(d) *Other limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(e) *Uses.* The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with the limitations in this section may be used as articles or components of articles intended for repeated food-contact use or as articles or components of articles intended for single-service food-contact use only under the conditions described in § 176.170(c) of this chapter, Table 2, conditions of use H.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984]

§ 177.2470 Polyoxymethylene copolymer.

Polyoxymethylene copolymer identified in this section may be safely used as an article or component of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene copolymers are identified as the following: The reaction product of trioxane (cyclic trimer of formaldehyde) and ethylene oxide (CAS Reg. No. 24969-25-3) or the reaction product of trioxane (cyclic trimer of formaldehyde) and a maximum of 5 percent by weight of butanediol formal (CAS Reg. No. 25214 85-1). Both copolymers may have certain optional substances added to impart desired technological properties to the copolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene copolymer identified in paragraph (a) of this section may contain optional adjuvant substances required in its production. The quantity of any optional adjuvant substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in Parts 170 through 189 of this chapter, and the following:

(1) Stabilizers (total amount of stabilizers not to exceed 2.0 percent and amount of any one stabilizer not to exceed 1.0 percent of polymer by weight)

Calcium ricinoleate.
Cyanoguanidine.
Hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).
Melamine-formaldehyde resin.
2,2'-Methylenebis(4-methyl-6-*tert*-butylphenol).
Nylon 6/66, weight ratio 2/3.
Tetrakis [methylene (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane.

(2) Lubricant: N,N'Distearoylethylenediamine.

(c) *Specifications.* (1) Polyoxymethylene copolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the copolymer is 15,000 as determined by a method titled "Number Average Molecular Weight," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *Extractive limitations.* (1) Polyoxymethylene copolymer in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature as determined from Tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene copolymer with or without the optional substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield total extractives as follows:

(i) Not to exceed 0.20 percent by weight of the copolymer when extracted for 6 hours with distilled water at reflux temperature.

(ii) Not to exceed 0.15 percent by weight of the copolymer when extracted for 6 hours with n-heptane at reflux temperature.

(e) *Conditions of use.* (1) The polyoxymethylene copolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250°F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene copolymer shall be thoroughly cleansed before their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 56204, Dec. 20, 1983; 49 FR 5748, Feb. 15, 1984; 50 FR 1842, Jan. 14, 1985; 50 FR 20560, May 17, 1985; 52 FR 4493, Feb. 12, 1987]

§ 177.2480 Polyoxymethylene homopolymer.

Polyoxymethylene homopolymer identified in this section may be safely used as articles or components of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene homopolymer is polymerized formaldehyde [Chemical Abstracts Service Registry No. 9002-81-7]. Certain optional adjuvant substances, described in paragraph (b) of this section, may be added to impart desired technological properties to the homopolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene homopolymer identified in paragraph (a) of this section may contain optional adjuvant substances in its production. The quantity of any optional adjuvant substance employed in the production of the homopolymer does not exceed the amount reasonably required to accomplish the intended effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

(1) *Stabilizers.* The homopolymer may contain one or more of the following stabilizers. The total amount of stabilizers shall not exceed 1.9 percent of homopolymer by weight, and the quantity of individual stabilizer used shall not exceed the limitations set forth below:

Substances	Limitations
Hexamethylenebis(3.5-di-*tert*-butyl-4-hydroxy-hydrocinnamate) (CAS Reg. No. 35074-77-2).	At a maximum level of 1 percent by weight of homopolymer. The finished articles shall not be used for foods containing more than 8 percent alcohol.
2,2'-Methylenebis(4-methyl-6-*tert*-butylphenol).	At a maximum level of 0.5 percent by weight of homopolymer.

Substances	Limitations
Nylon 66/610/6 terpolymer, respective proportions of nylon polymers by weight are: 3/2/4.	At a maximum level of 1.5 percent by weight of homopolymer.
Nylon 612/6 copolymer (CAS Reg. No. 51733-10-9), weight ratio 6/1.	Do.
Tetrakis[methylene(3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate)] methane.	At a maximum level of 0.5 percent by weight of homopolymer.

(2) *Lubricant.* *N,N'*-Distearoylethylenediamine.

(3) *Molding assistant.* Polyethylene glycol 6,000.

(c) *Specifications.* (1) Polyoxymethylene homopolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the homopolymer is 25,000.

(3) Density of the homopolymer is between 1.39 and 1.44 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) Melting point is between 172° C and 184° C as determined by ASTM method D2133-66, "Specifications for Acetal Resin Injection Molding and Extrusion Materials" (Revised 1966), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *Extractive limitations.* (1) Polyoxymethylene homopolymer, in the finished form which is to contact food, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of intended use under paragraphs (c)(3) and (d) of § 175.300 of this chapter and as limited by paragraph (e) of this section, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene homopolymer, with or without the optional adjuvant substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield extractives as follows:

(i) Formaldehyde not to exceed 0.0050 percent by weight of homopolymer as determined by a method titled "Formaldehyde Release and Formaldehyde Analysis," which is incorporated by reference. Copies are available from Division of Food and Color Additives, Bureau of Foods (HFF-330) Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(ii) Total extractives not to exceed 0.20 percent by weight of homopolymer when extracted for 6 hours with distilled water at reflux temperature and 0.15 percent by weight of homopolymer when extracted for 6 hours with *n*-heptane at reflux temperature.

(e) *Conditions of use.* (1) Polyoxymethylene homopolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250° F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene homopolymer shall be thoroughly cleansed prior to first use in contact with food.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 44835, Sept. 29, 1978; 47 FR 11846, Mar. 19, 1982; 47 FR 51562, Nov. 16, 1982; 49 FR 10111, Mar. 19, 1984]

§ 177.2490 Polyphenylene sulfide resins.

Polyphenylene sulfide resins (poly(1,4-phenylene sulfide) resins) may be safely used as coatings or components of coatings of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions.

(a) Polyphenylene sulfide resins consist of basic resins produced by the reaction of equimolar parts of *p*-dichlorobenzene and sodium sulfide, such that the finished resins meet the following specifications as determined by methods titled "Oxygen Flask Combustion-Gravimetric Method for Determination of Sulfur in Organic Compounds," "Determination of the Inherent Viscosity of Polyphenylene Sulfide," and "Analysis for Dichlorobenzene in Ryton Polyphenylene Sulfide," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(1) Sulfur content: 28.2-29.1 percent by weight of finished resin.

(2) Minimum inherent viscosity: 0.13 deciliters per gram.

(3) Maximum residual *p*-dichlorobenzene: 0.8 ppm.

(b) Subject to any limitations prescribed in Parts 170 through 189 of this chapter, the following optional substances may be added to the polyphenylene sulfide basic resins in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect.

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with prior sanction or approval.

(3) Substances the use of which is permitted in coatings under regulations in Parts 170 through 189 of this chapter.

(c) The finished coatings are thermally cured at temperatures of 700° F and above.

(d) Polyphenylene sulfide resin coatings may be used in contact with food at temperatures not to exceed the boiling point of water; provided that the finished cured coating, when extracted at reflux temperatures for 8 hours separately with distilled water, 50 percent ethanol in water, and 3 percent acetic acid, yields total extractives in each extracting solvent not to exceed 0.02 milligram per square inch of surface and when extracted at reflux temperature for 8 hours with heptane yields total extractives not to exceed 0.1 milligram per square inch of surface.

(e) Polyphenylene sulfide resin coatings containing perfluorocarbon resins complying with § 177.1550 may be used in contact with food at temperatures up to and including normal baking and frying temperatures; provided that the finished cured coating, when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol in water, 3 percent acetic acid and heptane, yields total extractives in each extracting solvent not to exceed 0.2 milligram per square inch of surface and when extracted at reflux temperature for 1 hour with diphenyl ether yields total extractives not to exceed 4.5 milligrams per square inch of surface.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11846, Mar. 19, 1982]

§ 177.2510 Polyvinylidene fluoride resins.

Polyvinylidene fluoride resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polyvinylidene fluoride resins consist of basic resins produced by the polymerization of vinylidene fluoride.

(b) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the solvents distilled water, 50 percent (by volume) ethyl alcohol in distilled water, and *n*-heptane, yields total extractives in each extracting solvent not to exceed 0.01 milligram per square inch of food-contact surface tested; and if the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(c) In accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene fluoride resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2550 Reverse osmosis membranes.

Substances identified in paragraph (a) of this section may be safely used as reverse osmosis membranes intended for use in processing bulk quantities of liquid food to separate permeate from food concentrate or in purifying water for food manufacturing under the following prescribed conditions:

(a) *Identity.* For the purpose of this section, the reverse osmosis membrane consists of a cross-linked high molecular weight polyamide identified as 1,3,5-benzene-tricarbonyl trichloride polymer with 1,3-benzenediamine (CAS Reg. No. 83044-99-9). The membrane is on the food-contact surface, and its maximum weight is 62 milligrams per square decimeter (4 milligrams per square inch) as a thin film composite on a suitable support.

(b) *Optional adjuvant substances.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymer. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Supports.* Suitable supports for reverse osmosis membranes are materials permitted for such use by regulations in Parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(d) *Conditions of use.* (1) Reverse osmosis membranes described in paragraph (a) of this section may be used in contact with all types of liquid food at temperatures up to 80 ° C (176 ° F).

(2) Reverse osmosis membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice so as to prevent microbial adulteration of food.

(3) To assure their safe use, reverse osmosis membranes and their supports shall be thoroughly cleaned prior to their first use in accordance with current good manufacturing practice.

[49 FR 49448, Dec. 20, 1984]

§ 177.2600 Rubber articles intended for repeated use.

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section.

(b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.

(c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances that by regulation in Parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation.

(4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(i) *Elastomers.*

Acrylonitrile-butadiene copolymer.

Butadiene-acrylonitrile-ethylene glycol dimethacrylate copolymers containing not more than 5 weight percent of polymer units derived from ethylene glycol dimethacrylate.

Butadiene-acrylonitrile-methacrylic acid copolymer.

Butadiene-styrene-methacrylic acid copolymer.

Chloroprene polymers.

Chlorotrifluoroethylene-vinylidene fluoride copolymer.

Ethylene-propylene copolymer elastomers which may contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene.

Ethylene-propylene-dicyclopentadiene copolymer.

Ethylene propylene-1,4-hexadiene copolymers containing no more than 8 weight percent of total polymer units derived from 1,4-hexadiene.

Isobutylene-isoprene copolymer.

Polybutadiene.

Polyester elastomers derived from the reaction of dimethyl terephthalate, 1,4-butanediol, and α-hydro-*omega*-hydroxypoly(oxytetramethylene); for use only in contact with foods containing not more than 8 percent alcohol and limited to use in contact with food at temperatures not exceeding 150° F.

Polyisoprene.

Polyurethane resins derived from reactions of diphenylmethane diisocyanate with adipic acid and 1,4-butanediol.

Rubber, natural.

Silicone basic polymer as described in ASTM method D1418-81, "Standard Practice for Rubber and Rubber Latices—Nomenclature," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Silicone (Si) elastomers containing methyl groups.

Silicone (Psi) elastomers containing methyl and phenyl groups.

Silicone (Vsi) elastomers containing methyl and vinyl groups.

Silicone (Fsi) elastomers containing methyl and fluorine groups.

Silicone (PVsi) elastomers containing phenyl, methyl, and vinyl groups.

Styrene-butadiene copolymer.

Vinylidene fluoride-hexafluoropropylene copolymers (minimum number average molecular weight 70,000 as determined by osmotic pressure in methyl ethyl ketone).

Vinylidene fluoride-hexafluoropropylene-tetrafluoroethylene copolymers (minimum number average molecular weight 100,000 as determined by osmotic pressure in methyl ethyl ketone).

(ii) *Vulcanization materials*—(*a*) *Vulcanizing agents*.

4,4'-Bis(aminocyclohexyl)methane carbamate for use only as cross-linking agent in the vulcanization of vinylidene fluoride-hexafluoropropylene copolymer and vinylidene fluoride-hexafluoropropylene-tetrafluoroethylene copolymer elastomers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 2.4 percent by weight of such copolymers.

Hexamethylenediamine carbamate for use only as cross-linking agent in the vulcanization of vinylidene fluoride-hexafluoropropylene copolymer and vinylidene fluoride-hexafluoropropylene-tetrafluoroethylene copolymer elastomers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 1.5 percent by weight of such copolymers.

Sulfur, ground.

(*b*) *Accelerators (total not to exceed 1.5 percent by weight of rubber product).*

2-Benzothiazyl-*N,N*-diethylthiocarbamyl-sulfide.

Benzoyl peroxide.

1,3-Bis(2-benzothiazolylmercaptomethyl) urea.

N-tert-Butyl-2-benzothiazole sulfenamide.

Butyraldehyde-aniline resin (iodine number 670-705).

Carbon disulfide-1,1'-methylenedipiperidine reaction product.

Copper dimethyldithiocarbamate.

N-Cyclohexyl-2-benzothiazole sulfenamide.

Dibenzoyl-*p*-quinone dioxime.

Dibenzylamine.

Di-*tert*-butyl peroxide.

Dibutyl xanthogen disulfide.

2,4-Dichlorobenzoyl peroxide.

Dicumyl peroxide.

N,N-Dimethylcyclohexylamine salt of dibutyldithiocarbamic acid.

2,6-Dimethylmorpholine thiobenzothiazol.

Dipentamethylenethiuram tetrasulfide.

Diphenylguanidine.

Diphenylguanidine phthalate.

1,3-Diphenyl-2-thiourea.

2,2'-Dithiobis[benzothiazole].

4,4'-Dithiodimorpholine.

N,N'-Di-*o*-tolylguanidine.

Di-*o*-tolylguanidine salt of pyrocatecholborate.

Ethylenediamine carbamate.

Heptaldehyde-aniline resin (iodine number 430-445).

Hexamethylenetetramine.

2-Mercaptobenzothiazole.

2-Mercaptothiazoline.

N-Oxydiethylene-benzothiazole-2-sulfenamide.

Piperidinium pentamethylenedithiocarbamate.

Potassium pentamethylenedithiocarbamate.

p-Quinone dioxime.

Sodium dibutyldithiocarbamate.

Sodium dimethyldithiocarbamate.

Stannous oleate for use only as an accelerator for silicone elastomers.
Tetrabutylthiuram monosulfide.
Tetraethylthiuram disulfide.
(1,1,4,4-Tetramethyltetramethylene)bis [*tert*-butyl peroxide].
Tetramethylthiuram monosulfide.
Thiram (tetramethylthiuram disulfide).
Triallyl cyanurate.
Triethylenetetramine.
1,3,5-Triethyl-hexahydro-*s*-triaxine (triethyltrimethylenetriamine).
Triphenylguanidine.
Zinc butyl xanathate.
Zinc dibenzyl dithiocarbamate.
Zinc dibutyldithiocarbamate.
Zinc diethyldithiocarbamate.
Zinc 2-mercaptobenzothiazole.
Ziram (zinc dimethyldithiocarbamate).

(c) *Retarders (total not to exceed 10 percent of weight of rubber product).*

Cyanoguanidine.
Phthalic anhydride.
Salicylic acid.

(d) *Activators (total not to exceed 5 percent by weight of rubber product except magnesium oxide may be used at higher levels).*

Diethylamine.
Fatty acid amines, mixed.
Fatty acids.
Magnesium carbonate.
Magnesium oxide, light and heavy.
Oleic acid, dibutylamine salt (dibutylammonium oleate).
Stannous chloride.
Tall oil fatty acids.
Tetrachloro-*p*-benzoquinone.
Triethanolamine.
Zinc salts of fatty acids.

(iii) *Antioxidants and antiozonants (total not to exceed 5 percent by weight of rubber product).*

Aldol-α-naphthylamine.
Alkylated (C_8 and/or C_9) phenols.
BHT (butylated hydroxytoluene).
4-[[4,6-Bis(octylthio)-*s*-triazin-2-yl]amino]-2,6-di-*tert*-butylphenol (CAS Reg. No. 991-84-4) for use only as a stabilizer at levels not to exceed 0.2 percent by weight of the finished rubber product.
Butylated reaction product of *p*-cresol and dicyclopentadiene as identified in § 178.2010(b) of this chapter.
Butylated, styrenated cresols identified in § 178.2010(b) of this chapter.
4,4'-Butylidinebis(6-*tert*-butyl-*m*-cresol).
N-Cyclohexyl-*N'*-phenylphenylenediamine.
p,p'-Diaminodiphenylmethane.
2,5-Di-*tert*-amylhydroquinone.
Diaryl-*p*-phenylenediamine, where the aryl group may be phenyl, tolyl, or xylyl.
2,6-Di-*tert*-butyl-*p*-phenylphenol.
1,2-Dihydro-2,2,4-trimethyl-6-dodecylquinoline.
1,2-Dihydro-2,2,4-trimethyl-6-ethoxyquinoline.
1,2-Dihydro-2,2,4-trimethyl-6-phenylquinoline.
4,4'-Dimethoxydiphenylamine.
4,6-Dinonyl-*o*-cresol.
N,N'-Dioctyl-*p*-phenylenediamine.
Diphenylamine-acetone resin.
Diphenylamine-acetone-formaldehyde resin.
N,N'-Diphenylethylenediamine.
N,N'-Disalicylalpropylenediamine.
N,N'-Di-*o*-tolylethylenediamine.
Hydroquinone monobenzyl ether.
Isopropoxydiphenylamine.
N-Isopropyl-*N'*-phenyl-*p*-phenylenediamine.
2,2'-Methylenebis(6-*tert*-butyl-4-ethylphenol).
2,2'-Methylenebis(4-methyl-6-*tert*-butylphenol).
2,2'-Methylenebis(4-methyl-6-nonylphenol).
2,2'-Methylenebis(4-methyl-6-*tert*-octylphenol).
Monooctyl- and dioctyldiphenylamine.
N,N'-Di-β-naphthyl-*p*-phenylenediamine.
Phenyl-α-naphthylamine.
Phenyl-β-naphthylamine.
Phenyl-β-naphthylamine-acetone aromatic amine resin (average molecular weight 600; nitrogen content 5.3 percent).
o- and *p*-Phenylphenol.
Polybutylated (mixture) 4,4'-isopropylidenediphenol.
Sodium pentachlorophenate.
Styrenated cresols produced when 2 moles of styrene are made to react with 1 mole of a mixture of phenol and *o*-, *m*-, and *p*-cresols so that the final product has a Brookfield viscosity at 25° C of 1400 to 1700 centipoises.
Styrenated phenol.
4,4'-Thiobis (6-*tert*-butyl-*m*-cresol).
Toluene-2,4-diamine.
N-*o*-Tolyl-*N'*-phenyl-*p*-phenylenediamine.
p(*p*-Tolylsufanilamide) diphenylamine.
Tri(mixed mono- and dinonylphenyl) phosphite.
Tri(nonylphenyl) phosphite-formaldehyde resins produced when 1 mole of tri(nonylphenyl) phosphite is made to react with 1.4 moles of formaldehyde or produced when 1 mole of nonylphenol is made to react with 0.36 mole of formaldehyde and the reaction product is then further reacted with 0.33 mole of phosphorus trichloride. The finished resins have a minimum viscosity of 20,000 centipoises at 25° C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 12 r.p.m., and have an organic phosphorus content of 4.05 to 4.15 percent by weight.

(iv) *Plasticizers (total not to exceed 30 percent by weight of rubber product).*

n-Amyl *n*-decyl phthalate.
Butylacetyl ricinoleate.
n-Butyl ester of tall oil fatty acids.
Butyl laurate.
Butyl oleate.
Butyl stearate.
Calcium stearate.
Castor oil.
Coumarone-indene resins.
2,2'-Dibenzamidodiphenyl disulfide.
Dibenzyl adipate.
Dibutoxyethoxyethyl adipate.
Dibutyl phthalate.
Dibutyl sebacate.
Didecyl adipate.
Didecyl phthalate.
Diisodecyl adipate.
Diisodecyl phthalate.
Diisooctyl adipate.
Diisooctyl sebacate.
Dioctyl adipate.
Dioctyl phthalate.
Dioctyl sebacate.
Dipentene resin.
Diphenyl ketone.
Fatty acids.
Fatty acids, hydrogenated.
Isooctyl ester of tall oil fatty acids.
Lanolin.
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 *α*-methylstyrene to 3 vinyltoluene).
Mineral oil.
Montan wax.
n-Octyl *n*-decyl adipate.
n-Octyl *n*-decyl phthalate.
Petrolatum.
Petroleum hydrocarbon resin (cyclopentadiene type), hydrogenated.
Petroleum hydrocarbon resin (produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks).
Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).
Petroleum oil, sulfonated.
Phenol-formaldehyde resin.
Pine tar.
Polybutene.
Polystyrene.
Propylene glycol.
n-Propyl ester of tall oil fatty acids.
Rapeseed oil vulcanized with rubber maker's sulfur.
Rosins and rosin derivatives identified in § 175.105(c)(5) of this chapter.
Soybean oil vulcanized with rubber maker's sulfur.
Styrene-acrylonitrile copolymer.
Terpene resins.
Triethylene glycol dicaprate.
Triethylene glycol dicaprylate.
Waxes, petroleum.
Xylene (or toluene) alkylated with dicyclopentadiene.
Zinc 2-benzamidothiophenate.

(v) *Fillers.*

Aluminum hydroxide.
Aluminum silicate.
Asbestos fiber, chrysotile or crocidolite.
Barium sulfate.
Carbon black (channel process or furnace combustion process; total carbon black not to exceed 50 percent by weight of rubber product; furnace combustion black content not to exceed 10 percent by weight of rubber products intended for use in contact with milk or edible oils).
Cork.
Cotton (floc, fibers, fabric).
Mica.
Nylon (floc, fibers, fabric).
Silica.
Titanium dioxide.
Zinc carbonate.
Zinc sulfide.

(vi) *Colors (total not to exceed 10 percent by weight of rubber product).*

Chrome oxide (Cr_2O_3).
C.I. pigment red 38, C.I. No. 21120.
Iron oxide.
Phthalocyanine.
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Titanium dioxide.
Ultramarine blue.
Zinc chromate.

(vii) *Lubricants (total not to exceed 2 percent by weight of rubber product).*

Polyethylene.
Sodium stearate.

(viii) *Emulsifiers.*

Fatty acid salts, sodium or potassium.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.
Rosins and rosin-derivatives identified in § 175.105(c)(5) of this chapter.
Sodium decylbenzenesulfonate
Sodium dodecylbenzenesulfonate
Sodium lauryl sulfate.
Tall oil mixed soap (calcium, potassium, and sodium).

(ix) *Miscellaneous (total not to exceed 5 percent by weight of rubber product).*

Animal glue as described in § 178.3120 of this chapter.

Azodicarbonamide as chemical blowing agent.
2-Anthraquinone sulfonic acid sodium salt for use only as polymerization inhibitor in chloroprene polymers and not to exceed 0.03 percent by weight of the chloroprene polymers.
n-Butyllithium for use only as polymerization catalyst for polybutadiene.
4-*tert*-Butyl-*o*-thiocresol as peptizing agent.
tert-Butyl peracetate.
p-*tert*-Butylpyrocatechol.
Dialkyl (C_8–C_{18}) dimethylammonium chloride for use only as a flocculating agent in the manufacture of silica.
Di- and triethanolamine.
Diethyl xanthogen disulfide.
4-(Diiodomethylsulfonyl) toluene, Chemical Abstracts Service Registry No. 20018-09-01, for use as an antifungal preservative at levels not to exceed 0.3 percent by weight of the sealants and caulking materials.
Dodecyl mercaptan isomers, single or mixed.
2-Ethoxyethanol.
Iodoform.
p-Menthane hydroperoxide.
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters, barium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 moles; for use only as residual polymerization emulsifier at levels not to exceed 0.7 percent by weight of ethylene-propylene-1,4-hexadiene copolymers identified under paragraph (c)(4)(i) of this section.
4,4′-Oxybis (benzenesulfonhydrazide) as chemical blowing agent.
Phenothiazine.
Potassium persulfate.
Sodium formaldehyde sulfoxylate.
Sodium polysulfide.
Sodium nitrite.
Sodium salt of ethylenediamine tetraacetic acid and glycine.
Sodium sulfide.
Styrene monomer.
Tall oil.
Thioxylenols as peptizing agents.
Tridecyl mercaptan.
Zinc 4-*tert*-butylthiophenate as peptizing agent.

(d) Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

(e) Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

(f) Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with *n*-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

(g) In accordance with good manufacturing practice finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

(h) The provisions of this section are not applicable to rubber nursing-bottle nipples.

(i) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 16972, Apr. 21, 1978; 44 FR 52189, Sept. 7, 1979; 45 FR 67321, Oct. 10, 1980; 46 FR 46796, Sept. 22, 1981; 49 FR 4073, Feb. 2, 1984; 49 FR 10111, Mar. 19, 1984]

§ 177.2710 Styrene-divinylbenzene resins, cross-linked.

Styrene-divinylbenzene cross-linked copolymer resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The resins are produced by the copolymerization of styrene with divinylbenzene.

(b) The resins meet the extractives limitations prescribed in this paragraph:

(1) The resins to be tested are ground or cut into small particles that will pass through a U.S. standard sieve No. 3 and that will be held on a U.S. standard sieve No. 20.

(2) A 100-gram sample of the resins, when extracted with 100 milliliters of ethyl acetate at reflux temperature for 1 hour, yields total extractives not to exceed 1 percent by weight of the resins.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2800 Textiles and textile fibers.

Textiles and textile fibers may safely be used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The textiles and textile fibers are prepared from one or more of the fibers identified in paragraph (d) of this section and from certain other adjuvant substances required in the production of the textiles or textile fibers or added to impart desired properties.

(b) The quantity of any adjuvant substance employed in the production of textiles or textile fibers does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of textiles or textile fibers that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of or added to textiles and textile fibers may include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in textiles and textile fibers and used in accordance with such sanction or approval.

(3) Substances generally recognized as safe for use in cotton and cotton fabrics used in dry-food packaging.

(4) Substances that by regulation in this part may safely be used in the production of or as a component of textiles or textile fibers and subject to provisions of such regulation.

(5) Substances identified in this paragraph (d)(5), subject to such limitations as are provided:

List of substances	Limitations
(i) Fibers:	
Cotton	
Polyethylene terephthalate complying in composition with the provisions of § 177.1630(e)(4)(ii).	For use only in the manufacture of items for repeated use.
Rayon	
(ii) Adjuvant substances:	
Aluminum stearate	
4,4'-Bis(4-anilino-6-diethanolamine-*s*-triazin-2-ylamino)-2,2'-stilbene-disulfonic acid, disodium salt.	For use as colorant only.
Borax	For use as preservative only.
Butyl-acetyl ricinoleate	
Di-*tert*-butyl hydroquinone	
Dimethylpolysiloxane	
Ethylenediaminetetraacetic acid, sodium salt	
4-Ethyl-4-hexadecyl morpholinium ethyl sulfate	For use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(5)(i) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.
Eugenol	
Fats, oils, fatty acids, and fatty alcohols derived from castor, coconut, cottonseed, fish, mustardseed, palm, peanut, rapeseed, ricebran, soybean, sperm, and tall oils and tallow.	
Fats, oils, fatty acids, and fatty alcohols described in the preceding item reacted with one or more of the following substances:	
n-Butyl and isobutyl alcohol	

List of substances	Limitations
Diethylene glycol	
Diethanolamine	
Glycerol	
Hexylene glycol (2-methyl-2,4-pentanediol)	
Hydrogen	
Isopropyl alcohol	
Methyl alcohol	
Oxygen	
Polyethylene glycol (molecular weight 400–3,000)	
Potassium hydroxide	
Propylene glycol	
Sodium hydroxide	
Sulfuric acid	
Formaldehyde	For use as preservative only.
Glyceryl mono-12-hydroxystearate	
2-(8-Heptadecenyl)-1-[2-(10-octadecenamido)ethyl-2-imidazolinium ethyl sulfate.	
Hexylene glycol (2-methyl,-2,4-pentanediol)	
Isobutyl alcohol	
Isopropyl alcohol	
Kerosene	
Methyl ester of sulfated ricebran oil	
Mineral oil	For use only at a level not to exceed 0.15 percent by weight of finished fibers.
Mono- and diisopropylated *m*- and *p*-cresols (isothymol derivative).	
7-(2*H*-naphtho[1,2-*d*]triazol-2-yl)-3-phenylcoumarin [CAS Reg. No. 3333-62-8] having a melting point of 250° to 251° C and a nitrogen content of 10.7 to 11.2 percent.	For use only as an optical brightener in polyethylene terephthalate fibers specified in paragraph (d)(5)(i) of this section at a level not to exceed 0.035 percent by weight of the finished fibers.
N-Oleyl, *N′*-acetyl, *N′*-β-hydroxy-ethylenediamine	
Petrolatum	
Petroleum sulfonate	
Pine oil	
Polybutene, hydrogenated; complying with the identity prescribed under 21 CFR 178.3740(b) of this chapter.	
Polyethylene, oxidized (air blown)	
Polyvinyl acetate	
Polyvinyl alcohol	
Potassium soap of a saponified sulfated casto. oil	
Sodium bis(2,6-dimethylheptyl-4) sulfosuccinate	
Sodium dioctyl sulfosuccinate	
Sodium dodecyl benzenesulfonate	
Sodium fluoride	For use as preservative only.
Sodium hydrosulfite	
Sodium hypochlorite	
Sodium lauryl sulfate	
Sodium 2-mercaptobenzothiazole	Do.
Sodium pentachlorophenate	Do.
Styrene-butadiene copolymer	
Sulfated butyl, isobutyl and propyl oleate	
Tallow	
Tallow, sulfonated	
Titanium dioxide	
Triethanolamine	
Ultramarine blue	
Waxes, petroleum	
Zinc hydrosulfite	

(e) Textile and textile fibers are used as articles or components of articles that contact dry food only.

(f) The provisions of this section are not applicable to jute fibers used as prescribed by § 178.3620(d)(2) of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 37042, July 17, 1981; 49 FR 4372, Feb. 6, 1984; 49 FR 5748, Feb. 15, 1984]

§ 177.2910 Ultra-filtration membranes.

Ultra-filtration membranes identified in paragraph (a) of this section may be safely used in the processing of food, under the following prescribed conditions:

(a) The ultra-filtration membrane consists of paper impregnated with cured phenol-formaldehyde resin, which is used as a support and is coated with a vinyl chloride-acrylonitrile copolymer.

(b) Any substance employed in the production of ultra-filtration membranes that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the specifications of such regulation.

(c) Ultra-filtration membranes are used in the physical separation of dissolved or colloidally suspended varying molecular size components of liquids during the commercial processing of bulk quantities of food.

(d) Ultra-filtration membranes shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(e) To assure safe use of the ultra-filtration membranes, the label or labeling shall include adequate directions for a pre-use treatment, consisting of conditioning and washing with a minimum of 8 gallons of potable water prior to their first use in contact with food.

(f) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(Secs. 201(s), 402, 409, 701(a), 52 Stat. 1046-1047 as amended, 1055, 72 Stat. 1784-1788 (21 U.S.C. 321(s), 342, 348, 371(a)))

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Subpart A—[Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

Sec.
178.1005 Hydrogen peroxide solution.
178.1010 Sanitizing solutions.

Subpart C—Antioxidants and Stabilizers

178.2010 Antioxidants and/or stabilizers for polymers.
178.2550 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.
Sec.
178.2650 Organotin stabilizers in vinyl chloride plastics.

Subpart D—Certain Adjuvants and Production Aids

178.3010 Adjuvant substances used in the manufacture of foamed plastics.
178.3120 Animal glue.
178.3125 Anticorrosive agents.
178.3130 Antistatic and/or antifogging agents in food-packaging materials.
178.3280 Castor oil, hydrogenated.
178.3290 Chromic chloride complexes.
178.3295 Clarifying agents for polymers.
178.3297 Colorants for polymers.
178.3300 Corrosion inhibitors used for steel or tinplate.
178.3400 Emulsifiers and/or surface-active agents.
178.3450 Esters of stearic and palmitic acids.
178.3480 Fatty alcohols, synthetic.
178.3500 Glycerin, synthetic.
178.3505 Glyceryl tri-(12-acetoxystearate).
178.3520 Industrial starch-modified.
178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.
178.3550 Kaolin-modified.
178.3570 Lubricants with incidental food contact.
178.3600 Methyl glucoside-coconut oil ester.
178.3610 α-Methylstyrene-vinyltoluene resins, hydrogenated.
178.3620 Mineral oil.
178.3650 Odorless light petroleum hydrocarbons.
178.3690 Pentaerythritol adipate-stearate.
178.3700 Petrolatum.
178.3710 Petroleum wax.
178.3720 Petroleum wax, synthetic.
178.3730 Piperonyl butoxide and pyrethrins as components of bags.
178.3740 Plasticizers in polymeric substances.
178.3750 Polyethylene glycol (mean molecular weight 200-9,500).
178.3760 Polyethylene glycol (400) monolaurate.
178.3770 Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids.
178.3780 Polyhydric alcohol esters of long chain monobasic acids.
178.3790 Polymer modifiers in semirigid and rigid vinyl chloride plastics.
178.3800 Preservatives for wood.
178.3850 Reinforced wax.
178.3860 Release agents.
178.3870 Rosins and rosin derivatives.
178.3900 Sodium pentachlorophenate.
178.3910 Surface lubricants used in the manufacture of metallic articles.
178.3930 Terpene resins.

Sec.
178.3940 Tetraethylene glycol di-(2-ethylhexoate).
178.3950 Tetrahydrofuran.
178.3970 Ultramarine blue.

AUTHORITY: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

SOURCE: 42 FR 14609, Mar. 15, 1977, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

§ 178.1005 Hydrogen peroxide solution.

Hydrogen peroxide solution identified in this section may be safely used to sterilize polymeric food-contact surfaces identified in paragraph (e)(1) of this section.

(a) *Identity.* For the purpose of this section, hydrogen peroxide solution is an aqueous solution containing not more than 35 percent hydrogen peroxide (CAS Reg. No. 7722-84-1) by weight, meeting the specifications prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* Hydrogen peroxide solution identified in paragraph (a) of this section may contain substances generally recognized as safe in or on food, substances generally recognized for their intended use in food packaging, substances used in accordance with a prior sanction or approval, and substances permitted by applicable regulations in Parts 174 through 179 of this chapter.

(c) *Specifications.* Hydrogen peroxide solution shall meet the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 146-147, which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and the United States Pharmacopeia XX (1980), except that hydrogen peroxide may exceed the concentration specified therein.

(d) *Limitations.* No use of hydrogen peroxide solution in the sterilization of food-packaging material shall be considered to be in compliance if more than 0.1 part per million (ppm) of hydrogen peroxide can be determined in distilled water packaged under production conditions (assay to be performed immediately after packaging).

(e) *Conditions of use.* (1) Hydrogen peroxide solution identified in and complying with the specification in this section may be used by itself or in combination with other processes to treat food-contact surfaces prepared from ethylene-acrylic acid copolymers complying with § 177.1310 of this chapter, ionomeric resins complying with § 177.1330 of this chapter, ethylene-methyl acrylate copolymer resins complying with § 177.1340 of this chapter, ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter, olefin polymers complying with § 177.1520 of this chapter, polyethylene terephthalate polymers complying with § 177.1630 of this chapter (excluding polymers described in § 177.1630(c)), and polystyrene and rubber-modified polystyrene polymers complying with § 177.1640 to attain commercial sterility at least equivalent to that attainable by thermal processing for metal containers as provided for in Part 113 of this chapter.

(2) The packaging materials identified in paragraph (e)(1) of this section may be used for packaging all commercially sterile foods except that the olefin polymers may be used in articles for packaging foods only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, III, IV-B, V, and VI.

(3) Processed foods packaged in the materials identified in paragraph (e)(1) of this section shall conform with Parts 108, 110, 113, and 114 of this chapter as applicable.

[46 FR 2342, Jan. 9, 1981, as amended at 49 FR 10111, Mar. 19, 1984; 49 FR 32345, Aug. 14, 1984; 49 FR 37747, Sept. 26, 1984; 51 FR 45881, Dec. 23, 1986]

§ 178.1010 Sanitizing solutions.

Sanitizing solutions may be safely used on food-processing equipment and utensils, and on other food-contact articles as specified in this section, within the following prescribed conditions:

(a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.

(b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval.

(1) An aqueous solution containing potassium, sodium, or calcium hypochlorite, with or without the bromides of potassium, sodium, or calcium.

(2) An aqueous solution containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium, or calcium.

(3) An aqueous solution containing potassium iodide, sodium *p*-toluenesulfonchloroamide, and sodium lauryl sulfate.

(4) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloudpoint of 90°-100° C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and ethylene glycol monobutyl ether. Additionally, the aqueous solution may contain diethylene glycol monoethyl ether as an optional ingredient.

(5) An aqueous solution containing elemental iodine, hydriodic acid, α-(*p*-nonylphenyl)-*omega*-hydroxypoly-(oxyethylene) (complying with the identity prescribed in § 178.3400(c) and having a maximum average molecular weight of 748) and/or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900). Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.

(6) An aqueous solution containing elemental iodine, sodium iodide, sodium dioctylsulfosuccinate, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900).

(7) An aqueous solution containing dodecylbenzenesulfonic acid and either isopropyl alcohol or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(8) An aqueous solution containing elemental iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a minimum average molecular weight of 2,400 and α-lauroyl-*omega*-hydroxypoly (oxyethylene) with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. In addition to use on food-processing equipment and utensils, this solution may be used on beverage containers, including milk containers or equipment. Rinse water treated with this solution can be recirculated as a preliminary rinse. It is not to be used as final rinse.

(9) An aqueous solution containing *n*-alkyl (C_{12}-C_{16}) benzyldimethylammonium chloride compounds having average molecular weights of 351 to 380. The alkyl groups consist principally of groups with 12 to 16 carbon atoms and contain not more than 1 percent each of groups with 8 and 10 carbon atoms. Additionally, the aqueous solution may contain either ethyl alcohol or isopropyl alcohol as an optional ingredient.

(10) An aqueous solution containing trichloromelamine and either sodium lauryl sulfate or dodecyl- benzenesulfonic acid. In addition to use on food-processing equipment and utensils and other food-contact articles, this solution may be used on beverage containers except milk containers or equipment.

(11) An aqueous solution containing equal amounts of *n*-alkyl (C_{12}-C_{18}) benzyl dimethyl ammonium chloride and *n*- alkyl (C_{12}-C_{18}) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 384). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(12) An aqueous solution containing the sodium salt of sulfonated oleic acid, polyoxyethylene-polyoxypropylene block polymers (having an average molecular weight of 2,000 and 27 to 31 moles of polyoxypropylene). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding

milk. All equipment, utensils, glass bottles, and other glass containers treated with this sanitizing solution shall have a drainage period of 15 minutes prior to use in contact with food.

(13) An aqueous solution containing elemental iodine and alkyl (C_{12}-C_{15}) monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 70°-77°C in 1 percent aqueous solution and an average molecular weight of 807.

(14) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 90°-100°C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,000).

(15) An aqueous solution containing lithium hypochlorite.

(16) An aqueous solution containing equal amounts of *n*-alkyl (C_{12}-C_{18}) benzyl dimethyl ammonium chloride and *n*- alkyl (C_{12}-C_{14}) dimethyl ethylbenzyl ammonium chloride (having average molecular weights of 377 to 384), with the optional adjuvant substances tetrasodium ethylenediamin- etetraacetate and/or *alpha*-(*p*-nonylphenol)-*omega*-hydroxy poly (oxyethylene) having an average poly- (oxyethylene) content of 11 moles.

Alpha-hydro-omega-hydroxypoly-(oxyethylene) poly(oxypropoylene) (15 to 18 mole minimum) poly (oxyethylene) block copolymer, having a minimum molecular weight of 1,900 (CAS Registry No. 9003-11-6) may be used in lieu of alpha- (*p*-nonylphenol)-omega-hydroxy- poly(oxyethylene) having an av[erage] poly(oxyethylene) content of 11 moles. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(17) An aqueous solution containing di-*n*-alkyl(C_8-C_{10})dimethyl ammonium chlorides having average molecular weights of 332-361 and either ethyl alcohol or isopropyl alcohol. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(18) An aqueous solution containing *n*-alkyl(C_{12}-C_{18}) benzyldimethylammonium chloride, sodium metaborate, *alpha*-terpineol and *alpha*[*p*-(1,1,3,3-tetramethylbutyl)phenyl] -*omega*-hydroxy-poly (oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide.

(19) An aqueous solution containing sodium dichloroisocyanurate and tetrasodium ethylenediaminetetraacetate. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(20) An aqueous solution containing *ortho*-phenylphenol, *ortho*-benzyl-*para*-chlorophenol, para-tertiaryamylphenol, sodium -*alpha*-alkyl(C_{12}-C_{15})-*omega*-hydroxypoly (oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.

(21) An aqueous solution containing sodium dodecylbenzenesulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(22) An aqueous solution containing (1) di-*n*-alkyl(C_8-C_{10}) dimethylammonium chloride compounds having average molecular weights of 332-361, (2) *n*-alkyl (C_{12}-C_{18}) benzyldimethylammonium chloride compounds having average molecular weights of 351-380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

(23) An aqueous solution containing *n*-alkyl (C_{12}-C_{16}) benzyl-dimethylammonium chloride and didecyldimethylammonium chloride.

(24) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), *alpha*-[*p*-(1,1,3,3-tetramethylbutyl)-phenyl]-*omega*-hydroxypoly-(oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and *alpha*-alkyl(C_{12}-C_{15})-*omega*-hydroxy[poly(oxyethylene) poly(oxypropylene)] (having an average molecular weight of 965).

(25) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), potassium iodide (CAS Reg. No. 7681-11-0), and isopropanol (CAS Reg. No. 67-63-0). In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers and equipment and on food-contact surfaces in public eating places.

(26) [Reserved]

(27) An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), and sodium 1-octanesulfonate (CAS Reg. No. 5324-84-5). Additionally, the aqueous solution may contain isopropyl alcohol (CAS Reg. No. 67-63-0) as an optional ingredient.

(28) An aqueous solution containing sulfonated 9-octadecenoic acid (CAS Reg. No. 68988-76-1) and sodium xylenesulfonate (CAS Reg. No. 1300-72-7).

(29) An aqueous solution containing dodecyldiphenyloxidedisulfonic acid (CAS Reg. No. 30260-73-2), sulfonated tall oil fatty acid (CAS Reg. No. 68309-27-3), and neo-decanoic acid (CAS Reg. No. 26896-20-8). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(30) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1), peracetic acid (CAS Reg. No. 79-21-0), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4).

(31) An aqueous solution containing elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene) poly(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(32) An aqueous solution containing (i) di-*n*-alkyl(C_8-C_{10})dimethyl- ammonium chloride compounds having average molecular weights of 332 to 361, (ii) *n*-alkyl(C_{12}-C_{18})benzyldimethylammonium chloride compounds having average molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of groups with 8 and 10, (iii) ethyl alcohol, and (iv) *alpha*-(*p*-nonylphenyl)-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-nonylphenol with 9 to 12 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(33) An aqueous solution containing (i) di-*n*-alkyl-(C_8-C_{10})-dimethylammonium chloride compounds having average molecular weights of 332 to 361; (ii) *n*-alkyl(C_{12}-C_{18}) -benzyldimethylammonium chloride compounds having molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of the groups with 8 to 10; and (iii) tetrasodium ethylenediamine tetraacetate. Additionally, the aqueous solution contains either *alpha*-(*p*-nonylphenyl)-*omega*-hydroxypoly-(oxyethylene) or *alpha*-alkyl(C_{11}-C_{15})-*omega*-hydroxypoly-(oxyethylene), each produced with 9 to 13 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(c) The solutions identified in paragraph (b) of this section will not exceed the following concentrations:

(1) Solutions identified in paragraph (b)(1) of this section will provide not more than 200 parts per million of available halogen determined as available chlorine.

(2) Solutions identified in paragraph (b)(2) of this section will provide not more than 100 parts per million of available halogen determined as available chlorine.

(3) Solution identified in paragraph (b)(3) of this section will provide not more than 25 parts per million of titratable iodine. The solutions will contain the components potassium iodide, sodium *p*-toluenesulfonchloramide and sodium lauryl sulfate at a level not in excess of the minimum required to produce their intended functional effect.

(4) Solutions identified in paragraph (b)(4), (5), (6), (8), (13), and (14) of this

section will contain iodine to provide not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(5) Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million dodecylbenzenesulfonic acid and not more than 80 parts per million of polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800) or not more than 40 parts per million of isopropyl alcohol.

(6) Solutions identified in paragraph (b)(9) of this section shall provide when ready to use no more than 200 parts per million of the active quaternary compound.

(7) Solutions identified in paragraph (b)(10) of this section shall provide not more than sufficient trichloromelamine to produce 200 parts per million of available chlorine and either sodium lauryl sulfate at a level not in excess of the minimum required to produce its intended functional effect or not more than 400 parts per million of dodecylbenzenesulfonic acid.

(8) Solutions identified in paragraph (b)(11) of this section shall provide, when ready to use, not more than 200 parts per million of active quaternary compound.

(9) The solution identified in paragraph (b)(12) of this section shall provide not more than 200 parts per million of sulfonated oleic acid, sodium salt.

(10) Solutions identified in paragraph (b)(15) of this section will provide not more than 200 parts per million of available chlorine and not more than 30 ppm lithium.

(11) Solutions identified in paragraph (b)(16) of this section shall provide not more than 200 parts per million of active quaternary compound.

(12) Solutions identified in paragraph (b)(17) of this section shall provide, when ready to use, a level of 150 parts per million of the active quaternary compound.

(13) Solutions identified in paragraph (b)(18) of this section shall provide not more than 200 parts per million of active quaternary compound and not more than 66 parts per million of *alpha*[*p*-(1,1,3,3-tetramethylbutyl) phenyl]-*omega*-hydroxypoly (oxyethylene).

(14) Solutions identified in paragraph (b)(19) of this section shall provide, when ready to use, a level of 100 parts per million of available chlorine.

(15) Solutions identified in paragraph (b)(20) of this section are for single use applications only and shall provide, when ready to use, a level of 800 parts per million of total active phenols consisting of 400 parts per million *ortho*-phenylphenol, 320 parts per million *ortho*-benzyl-*para*-chlorophenol and 80 parts per million *para*-tertiaryamylphenol.

(16) Solution identified in paragraph (b)(21) of this section shall provide not more than 430 parts per million and not less than 25 parts per million of sodium dodecylbenzenesulfonate.

(17) Solutions identified in paragraph (b)(22) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compound.

(18) Solutions identified in paragraph (b)(23) of this section shall provide at least 150 parts per million and not more than 200 parts per million of the active quaternary compound.

(19) Solutions identified in paragraphs (b)(24) and (b)(25) of this section shall provide at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine shall not be in excess of the minimum amounts required to accomplish the intended technical effect.

(20)-(21) [Reserved]

(22) Solutions identified in paragraph (b)(27) of this section shall provide, when ready to use, at least 109 parts per million and not more than 218 parts per million of total active fatty acids and at least 156 parts per million and not more than 312 parts per million of the sodium 1-octanesulfonate.

(23) Solutions identified in paragraph (b)(28) of this section shall provide, when ready to use, at least 156 parts per million and not more than 312 parts per million of sulfonated 9-

octadecenoic acid, at least 31 parts per million and not more then 62 parts per million of sodium xylenesulfonate.

(24) Solutions identified in paragraph (b)(29) of this section will provide at least 237 parts per million and not more than 474 parts per million dodecyldiphenyloxidedisulfonic acid, at least 33 parts per million and not more than 66 parts per million sulfonated tall oil fatty acid, and at least 87 parts per million and not more than 174 parts per million neo-decanoic acid.

(25) Solutions identified in paragraph (b)(30) of this section shall provide, when ready to use, not less than 550 parts per million and not more than 1,100 parts per million hydrogen peroxide, not less than 100 parts per million and not more than 200 parts per million peracetic acid, not less than 150 parts per million and not more than 300 parts per million acetic acid, and not less than 15 parts per million and not more than 30 parts per million 1-hydroxyethylidene-1,1-diphosphonic acid.

(26) The solution identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(27) Solutions identified in paragraph (b)(32) of this section shall provide, when ready to use, at least 150 parts per million and no more than 400 parts per million of active quarternary compounds in solutions containing no more than 500 parts per million water hardness. The adjuvants used with the quarternary compounds will not exceed the amounts required to accomplish the intended technical effect.

(28) Solutions identified in paragraph (b)(33) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compounds. The adjuvants used with the quaternary compounds shall not exceed the amounts required to accomplish the intended technical effect. Tetrasodium ethylenediamine tetraacetate shall be added at a minimum level of 60 parts per million. Use of these sanitizing solutions shall be limited to conditions of water hardness not in excess of 300 parts per million.

(d) Sanitizing agents for use in accordance with this section will bear labeling meeting the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

[42 FR 14609, Mar. 16, 1977, as amended at 42 FR 37974, July 26, 1977; 42 FR 44544, Sept. 6, 1977; 43 FR 1941, Jan. 13, 1978; 45 FR 25389, Apr. 15, 1980; 45 FR 56787, Aug. 26, 1980; 46 FR 31006, June 12, 1981; 46 FR 60567, Dec. 11, 1981; 47 FR 53848, Nov. 30, 1982; 48 FR 6705, Feb. 15, 1983; 48 FR 23179, May 24, 1983; 48 FR 30613, July 5, 1983; 50 FR 23949, June 7, 1985; 50 FR 30148, July 24, 1985; 50 FR 40965, Oct. 8, 1985; 51 FR 7437 and 7438, Mar. 4, 1986; 51 FR 33892, Sept. 24, 1986; 51 FR 47226, Dec. 31, 1986; 52 FR 409, Jan. 6, 1987]

Subpart C—Antioxidants and Stabilizers

§ 178.2010 Antioxidants and/or stabilizers for polymers.

The substances listed in paragraph (b) of this section may be safely used as antioxidants and/or stabilizers in polymers used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

Substances	Limitations
N-n-Alkyl-*N'*-(carboxymethyl)-*N,N'*-trimethylenediglycine; the alkyl group is even numbered in the range C_{14}–C_{18} and the nitrogen content is in the range 5.4–5.6 weight percent.	For use only: 1. As component of nonfood articles complying with §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with § 177.1210 of this chapter or in coatings complying with § 175.300, § 176.170, or § 175.320 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch.
p-tert-Amylphenolformaldehyde resins produced when one mole of *p-tert*-amylphenol is made to react under acid conditions with one mole of formaldehyde.	For use only at levels not to exceed 2.1 percent by weight of polyamide resins that are: 1. Derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine. 2. Used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter.
1,4-Benzenedicarboxylic acid, bis[2-(1,1-dimethylethyl)-6-[[3-(1,1-dimethylethyl)-2-hydroxy-5-methylphenyl]methyl]-4-methyl-phenyl]ester (CAS Reg. No. 57569–40–1)	For use only at levels not to exceed 0.075 percent by weight of olefin polymers complying with § 177.1520 of this chapter.
2-(2*H*-Benzotriazol-2-yl)-4-(1, 1, 3, 3-tetramethylbutyl) phenol (CAS Reg. No. 3147–75–9).	For use only at levels not to exceed 0.5 percent by weight of polycarbonate resins complying with § 177.1580 of this chapter: *Provided*, That the finished resins contact food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.
2,6-Bis(1-methylheptadecyl)-*p*-cresol	For use only at levels not exceeding 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. The average thickness of such polymers in the form in which they contact fatty food or food containing more than 8 percent of alcohol shall not exceed 0.004 inch.
4-[[4,6-Bis(octylthio)-*s*-triazin-2-yl]amino]-2, 6-di-*tert*-butylphenol (CAS Reg. No. 991–84–4).	For use only: 1. At levels not to exceed 0.5 percent hy weight in styrene block copolymers complying with § 177.1810 of this chapter: *Provided*, That the finished styrene block copolymers contact food identified as Types I, II, IV–B, VI, VII–B, and VIII in Table 1 of § 176.170(c) of this chapter under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.1 percent by weight in polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter: *Provided*, That the finched polystyrene and rubber-modified polystyrene polymer contact food only under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter. 3. In adhesives complying with § 175.105 of this chapter, and in pressure-sensitive adhesives complying with § 175.125 of this chapter, subject to the limitations noted in that section.
1,3-Butanediol	4. As provided in § 177.2600 of this chapter.
Butylated reaction product of *p*-cresol and dicyclopentadiene produced by reacting *p*-cresol and dicyclopentadiene in an approximate mole ratio of 1.5 to 1, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 percent.	For use only as components of nonfood articles complying with §§ 175.105 and 177.2600(c)(4)(iii) of this chapter.

Substances	Limitations
Butylated, styrenated cresols produced when equal moles of isobutylene, styrene, and a metacresol-paracresol mixture having a no more than 3° C distillation range including 202° C are made to react so that the final product meets the following specifications: Not less than 95 percent by weight of total alkylated phenols consisting of 13–25 percent by weight of butylated *m*- and *p*-cresols, 26–38 percent by weight of styrenated *m*- and *p*-cresols, 37–49 percent by weight of butylated styrenated *m*- and *p*-cresols, and not more than 10 percent by weight total of alkylated xylenols, alkylated *o*-cresol, alkylated phenol, and alkylated ethylphenol; acidity not more than 0.003 percent; and refractive index at 25° C of 1.5550–1.5650, as determined by ASTM method D1218–82, "Standard Test Method for Refractive Index and Refractive Dispersion of Hydrocarbon Liquids," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	For use only: 1. As provided in §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polystyrene, rubber-modified polystyrene, or olefin polymers complying with § 177.1520 (c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4, or complying with other sections in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, used in articles that contact food only unded the conditions described in § 176.170(c) of this chapter, Table 2, under conditions of use C through G.
2-*tert*-Butyl-α(3-*tert*-butyl-4-hydroxyphenyl)-*p*-cumenyl bis(*p*-nonylphenyl) phosphite; the nonyl group is a propylene trimer isomer and the phosphorus content is in the range 3.8–4.0 weight percent.	For use only: 1. As components of nonfood articles complying with §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with § 177.1210 of this chapter or in coatings complying with § 175.300, § 175.320, or § 176.170 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch.
2-(3′-*tert*-Butyl-2′-hydroxy-5′-methyl-phenyl)-5-chlorobenzotriazole with a melting point of 137–141°C.	For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, provided that the finished polymer contacts foods only of the types identified in Categories I, II, IV-B, VI-A and B, VII-B, and VIII in Table 1, § 176.170 of this chapter.
4,4′-Butylidenebis(6-*tert*-butyl-*m*-cresol)	For use only. 1. As provided in §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polypropylene complying with § 177.1520 of this chapter and for use at levels not to exceed 0.3 percent by weight of polyethylene complying with § 177.1520 of this chapter, provided that the finished polypropylene and polyethylene contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, VI–B, and VIII.
Butyric acid, 3,3-bis(3-*tert*-butyl-4-hydroxyphenyl)ethylene ester (CAS Reg. No. 32509–66–3).	For use only: 1. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1 and 3.2 except that when used in contact with foods described as types III, IV–A, V, VII–A, and IX in Table 1 of § 176.170(c) of this chapter, the olefin copolymers may only be used under conditions of use E, F, and G set forth in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight-percent of polymer units derived from propylene). 3. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 3.1, and 3.2.
Calcium benzoate	
Calcium bis[monoethyl(3,5-di-*tert*-butyl-4-hydroxybenzyl)phosphonate] (CAS Reg. No. 65140–91–2).	For use only: 1. At levels not to exceed 0.25 percent by weight of polypropylene that complies with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3. 2. At levels not to exceed 0.2 percent by weight of polyethylene and olefin copolymers that comply with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, and 3.2 that have a density greater than 0.94 gram per cubic centimeter. 3. In adhesives complying with § 175.105 of this chapter. 4. At levels not to exceed 0.5 percent by weight of pressure-sensitive adhesives complying with § 175.125 of this chapter.

Substances	Limitations
	5. At levels not to exceed 0.5 percent by weight of rosins and rosin derivatives complying with § 175.300(b)(3)(v) of this chapter. 6. At levels not to exceed 0.5 percent by weight of can end cement formulations complying with § 175.300(b)(3)(xxxi) of this chapter. 7. At levels not to exceed 0.5 percent by weight of side seam cement formulations complying with § 175.300(b)(3)(xxxii) of this chapter. 8. At levels not to exceed 0.5 percent by weight of petroleum alicyclic hydrocarbon resins complying with § 175.320(b)(3) of this chapter. 9. At levels not to exceed 0.5 percent by weight of rosin and rosin derivatives complying with § 176.170(a)(5) of this chapter; and petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with § 176.170(b)(2) of this chapter. 10. At levels not to exceed 0.5 percent by weight of resins and polymers used as components of paper and paperboard in contact with dry food in compliance with § 176.180 of this chapter. 11. At levels not to exceed 0.5 percent by weight of closures with sealing gaskets complying with § 177.1210 of this chapter. 12. At levels not to exceed 0.5 percent by weight of the finished rubber article complying with § 177.2600 of this chapter. 13. At levels not to exceed 0.5 percent by weight of petroleum hydrocarbon resin and rosins and rosin derivatives complying with § 178.3800(b). 14. At levels not to exceed 0.5 percent by weight of reinforced wax complying with § 178.3850.
Calcium myristate	
Calcium ricinoleate	For use only at levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in § 177.2470(b)(1) of this chapter.
Calcium stearate	
Cupric acetate and lithium iodide	For use at levels not exceeding 0.025 percent cupric acetate and 0.065 percent lithium iodide by weight of nylon 66 resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250°F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0012 inch.
Cuprous iodide	For use at levels not exceeding 0.01 percent cuprous iodide by weight of nylon 66T resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250°F. The average thickness of such resins in the form in which they contact food shall not exceed 0.001 inch.
Cuprous iodide and cuprous bromide	For use at levels not exceeding 0.0025 percent cuprous iodide and 0.0175 percent cuprous bromide by weight of nylon 66 resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250°F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0015 inch.
Cyanoguanidine	For use only at levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in § 177.2470(b)(1) of this chapter.
Cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806-34-6); the phosphorus content is in the range of 7.8 to 8.2 weight percent.	For use only at levels not to exceed 0.1 percent by weight of ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter that contact food under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.
Cyclic neopentanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806-34-6) (which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122-20-3)); the phosphorus content is in the range of 7.8 to 8.2 weight percent.	For use only: 1. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 2.1, and 3.1. 2. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, that contact food Types I, II, VI-A, VII-B, and VIII described in Table 1 of § 176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 0.15 percent by weight of olefin polymers complying with § 177.1520, items 1.1 and 3.2, that contact food Types I, II, VI-A, VII-B, and VIII described in Table 1 of § 176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.20 percent by weight of polystyrene and/or rubber modified polystyrene complying with § 177.1640 of this chapter that contact food under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.

Substances	Limitations
4,4′-Cyclohexylidenebis(2-cyclohexylphenol)	For use only at levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4: *Provided*, That the finished polymers contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI, VII-B, and VIII.
Dicetyl thiodipropionate having a melting point of 59° –62° C as determined by ASTM method E324–79, "Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals," and a saponification value in the range 176–183 as determined by ASTM method D1962–67 (Reapproved 1979), "Standard Test Method for Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids," which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408..	The concentration of this additive and any other permitted antioxidants in the finished food-contact article shall not exceed a total of 0.5 milligram per square inch of food-contact surface.
2,6-Di(α-methyl benzyl)-4-methyl phenol [Chemical Abstracts Service Registry No. 1817–68–1].	For use only at levels not to exceed 0.2 percent by weight of olefin polymers complying with item 3.4 in § 177.1520(c) of this chapter, provided that such olefin polymers are limited to use at a level not to exceed 25 percent by weight in other olefin polymers complying with § 177.1520 of this chapter; and the total amount in such finished olefin polymers not to exceed 0.05 percent by weight, including the level that may be contributed by its presence at 6 percent in the item "butylated, styrenated cresols * * *" listed in this paragraph; and further provided that the finished olefin polymers are intended for contact with foods, except those containing more than 8 percent alcohol.
Dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol (CAS Reg. No. 65447–77–0).	For use only: 1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter: items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 when such finished polymers are used in repeat use articles: *Provided*, That the finished polymers contact food only under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter: *And further provided*, That such repeated use articles have a volume of at least 25 liters. 2. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter: Items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 when such finished polymers are used in single use articles: *Provided*, That the finished polymers contact food only under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.
Dimethyltin/monomethyltin isooctylmercaptoacetates consisting of 71 to 81 percent by weight of dimethyltin bis(isooctylmercaptoacetate) (CAS Reg. No. 26636–01–1), 19 to 29 percent by weight of monomethyltin tris (isooctylmercaptoacetate (CAS Reg. No. 54849–38–6), and no more than 0.4 percent by weight of trimethyltin compounds, and having the following specifications: Tin content (as Sn) in the range of 18.7 to 19.7 percent and mercaptosulfur content in the range of 11.5 to 12.5 percent. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. Other alkyltin compounds are not to exceed 20 ppm..	For use only at levels not to exceed 2.0 percent by weight: 1. In rigid polyvinyl chloride used in the manufacture of pipes intended for contact with water in food-processing plants, and 2. In rigid polyvinyl chloride and in rigid vinyl chloride copolymers complying with § 177.1950 of this chapter or § 177.1980 of this chapter for use in contact with food of Types I, II, III, IV (except liquid milk), V, VI, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.
Dimyristyl thiodipropionate having a melting point of 48° –52° C as determined by ASTM method E324–79, "Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals," and a saponification equivalent in the range 280–290 as determined by ASTM method D1962–67 (Reapproved 1979), "Standard Test Method for Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids," which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408..	Finished food-contact articles containing this additive shall meet the extractives limitations prescribed in § 176.170(c) of this chapter.

Substances	Limitations
Di(*n*-octyl)tin bis(2-ethylhexyl maleate) [CAS Reg. No. 10039-33-5] having 12.5 to 15.0 percent by weight of tin (Sn) and having a saponification number of 260 to 280. The additive is made from di(*n*-octyl)tin oxide meeting the specifications of § 178.2650(a)(1).	For use only at levels not to exceed 0.5 percent by weight of acrylonitrile copolymers complying with §§ 177.1020 and 177.1030 of this chapter and used in contact with all food types under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.
N,N-Diphenylthiourea	For use only: 1. At levels not to exceed 0.5 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 2. At levels not to exceed 0.5 percent by weight of vinyl chloride-vinyl acetate copolymers containing not more than 20 molar percent of vinyl acetate.
2,6-Di-*tert*-butyl-4-ethylphenol	For use only in contact with nonalcoholic foods: 1. At levels not exceeding 0.04 mg/in² of food contact surface and not exceeding 0.1 percent by weight in ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; § 177.1340; and § 177.1350 of this chapter. The average thickness of such polymers and copolymers in the form in which they contact food shall not exceed 0.0025 in. 2. At levels not exceeding 0.04 mg/in² of food contact surface in ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; § 177.1340; and § 177.1350 of this chapter. The average thickness of such polymers and copolymers in the form in which they contact food shall be greater than 0.0025 in but shall not exceed 0.025 in.
3,5-Di-*tert*-butyl-4-hyrtroxyhydrocinnamic acid triester with 1,3,5-tris(2-hydroxyethyl)-s-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione (CAS Reg. No. 34137-09-2).	For use only: 1. At levels not to exceed 0.5 percent by weight of polypropylene complying with § 177.1520 of this chapter in articles that contact food not in excess of high temperature heat-sterilized condition of use A described in § 176.170(c) of this chapter, Table 2. 2. At levels not to exceed 0.5 percent by weight of polyethylene complying with § 177.1520 of this chapter in articles that contact food not in excess of high temperature heat-sterilized condition of use A described in 176.170(c) of this chapter, Table 2. 3. In adhesives complying with § 175.105 of this chapter. 4. At levels not to exceed 0.25 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0.
Di-*tert*-butylphenyl phosphonite condensation product with biphenyl (CAS Reg. No. 38613-77-3) produced by the condensation of 2,4-di-*tert*-butylphenol with the Friedel-Crafts addition product (phosphorus trichloride and biphenyl) so that the food additive has a minimum phosphorus content of 5.4 percent, an acid value not exceeding 10 mg KOH/gm, and a melting range of 85 °C to 110 °C (185 °F to 230 °F).	For use only: 1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 2.1, 2.2, 3.1, or 3.2.
2,4-Di-*tert*-butylphenyl 3,5-di-*tert*-butyl-4-hydroxybenzoate (CAS Reg. No. 4221-80-1).	For use only: 1. At levels not to exceed 0.6 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1: (1) when used in single-use articles that contact food of types I, II, IV-B, VI-A, VI-B, VII-B, and VIII, identified in table 1 of § 176.170(c) of this chapter; and (2) when used in repeated-use articles that contact food of types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of § 176.170(c) of this chapter. The additive is used under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.25 percent by weight of olefin polymers having a density of not less than 0.94 gram per cubic centimeter and complying with § 177.1520(c) of this chapter, items 2.1 and 2.2: (1) when used in single-use articles that contact food of types I, II, IV-B, VI-A, VI-B, VII-B, and VIII, identified in table 1 of § 176.170(c) of this chapter; and (2) when used in repeated-use articles that contact food of types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of § 176.170(c) of this chapter. The additive is used under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
Ethylenebis(oxyethylene)-bis-(3-*tert*-butyl-4-hydroxy-5-methylhydrocinnamate) (CAS Reg. No. 36443-68-2).	1. At levels not to exceed 0.3 percent by weight of polystyrene and/or rubber modified polystyrene polymers complying with § 177.1640 of this chapter. 2. At levels not to exceed 0.3 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with applicable regulations in Parts 175, 176, 177, and 181 of this chapter.

Substances	Limitations
	3. At levels not to exceed 0.75 percent by weight of polyoxymethylene copolymers used in accordance with § 177.2470 of this chapter. The finished articles shall not be used for foods containing more than 15 percent alcohol. 4. At levels not to exceed 0.25 percent by weight of polyoxymethylene homopolymers used in accordance with § 177.2480 of this chapter. The finished articles shall not be used for foods containing more than 15 percent alcohol. 5. At levels not to exceed 0.2 percent by weight of rigid vinyl chloride plastics prepared from vinyl chloride homopolymers and/or vinly chloride copolymers used in accordance with a prior sanction or applicable regulations in Parts 175, 176, and 177 of this chapter. The vinyl chloride copolymers shall contain not less than 50 weight percent of total polymer units derived from vinyl chloride. 6. At levels not to exceed 0.1 percent by weight of vinylidene chloride homopolymers and/or vinylidene chloride copolymers used in accordance with a prior sanction or applicable regulations in Parts 175, 176, and 177 of this chapter. The vinylidene chloride copolymers shall contain not less than 50 weight percent of total polymer units derived from vinylidene chloride. 7. In adhesives used in accordance with § 175.105 of this chapter.
2,2'-Ethylidenebis(4,6-di-*tert*-butylphenol) (CAS Reg. No. 35958-30-6)	For use only: 1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 3.1, or 3.2 (where the polymers complying with items 3.1 and 3.2 contain primarily polymer units derived from propylene). 2. At levels not to exceed 0.05 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, or 2.3. The finished polymers are to be used only under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 0.075 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, or 2.3 (where the density of each of these polymers is not less than 0.94 g/cc) and item 3.1 or 3.2 (where each of these polymers contains primarily polymer units derived from ethylene). 4. At levels not to exceed 0.05 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 3.3, 3.4, 3.5, or 4. 5. At levels not to exceed 0.1 percent by weight of ethylene vinyl acetate copolymers complying with § 177.1350 of this chapter and under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter. 6. At levels not to exceed 0.1 percent by weight of rigid or semirigid polyvinyl chloride and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. 7. At levels not to exceed 0.2 percent by weight of acrylonitrile-butadiene-styrene copolymers containing less than 30 percent by weight of acrylonitrile and under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter. 8. At levels not to exceed 0.1 percent by weight of polystyrene complying with § 177.1640 of this chapter and under conditions of use D through G described in table 2 of § 176.170(c) of this chapter. 9. At levels not to exceed 0.2 percent by weight of rubber-modified polystyrene complying with § 177.1640 of this chapter. 10. In adhesives complying with § 175.105 of this chapter.
Hexadecyl 3,5-di-*tert*-butyl-4-hydroxybenzoate (CAS Reg. No. 67845-93-6).	For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520 of this chapter.
Hexamethylenebis (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).	As provided in §§ 177.2470(b)(1) and 177.2480(b)(1) of this chapter.
N,N'-Hexamethylenebis (*3,5-di-tert*-butyl-4-hydroxyhydrocinnamamide) (CAS Reg. No. 23128-74-7).	For use only: 1. At levels not to exceed 1 percent by weight of nylon resins complying with § 177.1500(b) of this chapter, items 1 through 8, that contact food only of the types identified in categories in § 176.170(c) of this chapter, Table 1 except VI-A and VI-C.

Substances	Limitations
	2. At levels not to exceed 0.75 percent by weight of nylon 12 resins complying with § 177.1500(b) of this chapter, item 9, that contact food only of the types identified in categories in § 176.170(c) of this chapter, Table 1, except VI–A and VI–C. 3. At levels not to exceed 0.6 percent by weight of polyester resins complying with § 175.300(b)(3)(vii) of this chapter. 4. At levels not to exceed 0.6 percent by weight of closures with sealing gaskets complying with § 177.1210 of this chapter. 5. At levels not to exceed 0.6 percent by weight of repeated use rubber articles complying with § 177.2600 of this chapter.
Hydrogenated 4,4′-isopropylidene-diphenolphosphite ester resins produced by the condensation of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated 4,4′-isopropylidene-diphenol such that the finished resins have a molecular weight in the range of 2,400–3,000, a phosphorous content of 6.5–6.9 percent, and contain no more than 2.2 percent by weight of residual free phenol.	For use only at levels not to exceed 0.55 percent by weight of vinyl chloride copolymers complying with § 177.1980 of this chapter and/or polyvinyl chloride when such vinyl chloride homo-and/or copolymers are used in the manufacture of rigid vinyl chloride plastic bottles intended for contact with edible oils (including edible oil in simple mixture or emulsion form), all types of dressings for salads, and food of Types VIII and IX described in Table 1 of § 176.170(c) of this chapter. The finished food-contact article containing this stabilizer, when extracted with distilled water at 135 °F for 1 week (168 hours), using a volume-to-surface ratio of 5 milliliters per square inch of surface tested, shall yield extracted phenol not to exceed 0.008 milligram per square inch of food-contact surface and shall yield extracted organophosphates (total phosphates minus inorganic phosphates) not to exceed 0.0001 milligram per square inch of food-contact surface.
2-Hydroxy-4-isooctoxy-benzophenone. Chemical Abstracts (CA) name: Methanone, [2-hydroxy-4-(isooctyloxy) phenyl]phenyl; CA Registry No. 33059–05–1.	For use only at levels not to exceed 0.5 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter: Items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3 or 4: *Provided*, That the finished polymer contacts food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, VII-B and VIII under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.
2(2′-Hydroxy-5′-methylphenyl)benzotriazole meeting the following specification: melting point 126°–132 °C (258.8°–269.6 °F) (CAS Reg. No. 2440–22–4)	For use only: 1. As component of nonfood articles complying with § 177.1010 of this chapter. 2. At levels not to exceed 0.25 percent by weight of rigid polyvinyl chloride and/or rigid vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. In polystyrene that complies with § 177.1640 of this chapter and that is limited to use in contact with dry food of Type VIII described in Table 1 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.25 percent by weight of polystyrene and/or rubber-modified polystyrene polymers complying with § 177.1640 of this chapter intended to contact nonalcoholic food: *Provided*, That the finished basic rubber-modified polystyrene polymers in contact with fatty foods shall contain not less than 90 weight percent of total polymer units derived from styrene monomer. 5. At levels not to exceed 0.5 percent by weight of polycarbonate resins complying with § 177.1580 of this chapter. *Provided*, That the finished polycarbonate resins contact food only of Types I, II, III, IV, V, VI–A, VI–B, VII, VIII, and IX identified in Table 1 of § 176.170(c) of this chapter and under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. 6. At levels not to exceed 0.5 percent by weight of ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers complying with § 177.1315 of this chapter and of ethylene phthalate polymers complying with § 177.1630 of this chapter and that contact food only under conditions of use D through G described in Table 2, § 176.170(c) of this chapter.
2-Hydroxy-4-*n*-octoxy-benzophenone	For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. *Provided*, That the finished polymer contacts food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, IV-B, VII-B, and VIII, and under the conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
4,4′-Isopropylidenediphenol alkyl(1C_{12}–C_{15}) phosphites; the phosphorus content is in the range of 5.2–5.6 weight percent.	For use only at levels not exceeding 1.0 percent by weight in rigid polyvinyl chloride and/or rigid vinyl chloride copolymers complying with §§ 177.1950, 177.1970 or 177.1980 of this chapter, and used in contact with food, except milk, only under the conditions described in § 176.170(c) of this chapter, Table 2, under conditions of use D through G.

Substances	Limitations
Magnesium salicylate	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: *Provided*, That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers.
2,2′-Methylenebis (6-*tert*-butyl-4-ethylphenol)	For use only: 1. In acrylonitrile-butadiene-styrene copolymers at levels not to exceed 0.6 percent by weight of the copolymer. 2. In semirigid and rigid acrylic and modified acrylic plastics complying with § 177.1010 of this chapter at levels not to exceed 0.1 percent by weight of the plastic.
4,4′-Methylenebis (2,6-di-*tert*-butyl-phenol)	For use only: 1. As provided in § 175.105 of this chapter. 2. At levels not to exceed 0.25 percent by weight of petroleum hydrocarbon resins used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 3. At levels not to exceed 0.25 percent by weight of terpene resins used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 4. At levels not to exceed 0.5 percent by weight of polyethylene complying with § 177.1520 of this chapter: *Provided*, That the polyethylene end product contacts foods only of the types identified in Categories I, II, IV-B, VI, VII-B, and VIII in Table 1, § 176.170(c) of this chapter. 5. At levels not to exceed 0.5 percent by weight of polybutadiene used in rubber articles complying with § 177.2600 of this chapter: *Provided*, That the rubber end product contacts foods only of the types identified in Categories I, II, IV-B, VI, VII-B, and VIII in Table 1, § 176.170(c) of this chapter.
2,2′-Methylenebis(4-methyl-6-*tert*-butylphenol)	For use only: 1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with sec. 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 used in articles that contact food of the types identified in sec. 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI, VII-B, and VIII. 2. At levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in sec. 177.2470(b)(1) of this chapter. 3. At levels not to exceed 0.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1) of this chapter.
2,2′-Methylenebis[6-(1-methylcyclo-hexyl)-*p*-cresol]	For use only: 1. As provided in § 177.1210 of this chapter. 2. At levels not to exceed 0.2 percent by weight of polyethylene complying with § 177.1520 of this chapter: *Provided*, That the finished polyethylene contacts foods only of the type identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, VI-B, and VIII. 3. In polyethylene complying with § 177.1520 of this chapter: *Provided*, That the finished polyethylene contacts foods only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV, V, VI-A, VII, and IX, and only at temperatures not to exceed room temperature: *And further provided*, That percentage concentration of the antioxidant in the polyethylene, when multiplied by the thickness in inches of the finished polyethylene, shall not be greater than 0.0005.
2,2′-Methylenebis(4-methyl-6-nonylphenol) and 2,6-bis(2-hydroxy-3-nonyl-5-methyl-benzyl)-*p*-cresol mixtures (varying proportions).	For use only in acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods.
Nylon 66/610/6 terpolymer (see § 177.1500 of this chapter for identification).	For use only at levels not to exceed 1.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480 (b)(1) of this chapter.
Nylon 612/6 copolymer. (CAS Reg. No. 51733–10–9), weight ratio 6/1.	For use only at levels not to exceed 1.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1).
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082–79–3).	For use only: 1. At levels not exceeding 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. 2. As provided in §§ 175.105 and 177.1010(a)(5) of this chapter. 3. At levels not exceeding 0.25 percent by weight of polystyrene and/or rubber-modified polystyrene polymers complying with § 177.1640 of this chapter, except that the finished basic rubber-modified polystyrene polymers in contact with fatty foods shall contain not less than 85 weight percent of total polymer units derived from styrene monomer.

Substances	Limitations
	4. At levels not to exceed 0.5 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with prior sanction or regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 5. At levels not exceeding 0.25 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, items 3.4 and 3.5 as follows: (a) item 3.4, *Provided*, That the finished copolymer contacts foods only of types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, III, IV-B, VI, VII, VIII, and IX; (b) item 3.5, *Provided*, That the finished copolymer contacts non-fatty foods only of types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI, VII-B, and VIII. 6. At levels not exceeding 0.05 percent by weight of modified semi-rigid and rigid vinyl chloride plastics modified with methacrylate-butadiene-styrene copolymers in accordance with § 178.3790. 7. At levels not exceeding 0.2 percent by weight of rigid polyvinyl chloride. 8. At levels not to exceed 0.3 percent by weight of polycarbonate resins that comply with § 177.1580 and that contact food only under conditions of use E, F, and G described in Table 2, § 176.170(c) of this chapter. 9. At levels not exceeding 0.1 percent by weight of ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter. 10. At levels not to exceed 0.2 percent by weight of nitrile rubber-modified acrylonitrile-methyl acrylate copolymers that comply with § 177.1480 of this chapter when used in articles that contact food only under conditions of use D, E, F, and G described in Table 2, § 176.170(c) of this chapter. 11. At levels not exceeding 0.3 percent by weight of styrene block polymers complying with § 177.1810 of this chapter when used in articles that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI, VII-B, and VIII, and under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter. 12. At levels not exceeding 0.2 percent by weight of vinylidene chloride homopolymers and/or vinylidene chloride copolymers complying with applicable regulations in Parts 175, 176, 177, 179, and 181 of this chapter. The vinylidene chloride copolymers shall contain not less than 50 weight percent of total polymer units derived from vinylidene chloride. 13. At levels not exceeding 0.025 percent by weight of chlorinated isobutylene-isoprene copolymers complying with § 177.1420(a)(3) of this chapter.
2,2'-Oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1)	For use only: 1. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3. 3. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0 that contact food Types I, II, IV-B, VI, VII-B and VIII described in Table 1 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, and 4.0 that contact food Types III, IV-A, V, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with items 3.1 and 3.2 where the majority of polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent by weight. 5. At levels not to exceed 0.1 percent by weight of olefin polymers complying with item 3.4 of § 177.1520(c) of this chapter, that contact food Types III, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter, except that olefin copolymers complying with item 3.4 where the majority of the polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent by weight.
Pentaerythritol and its stearate ester	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: *Provided*, That the total amount of pentaerythritol and/or pentaerythritol stearate (calculated as free pentaerythritol) does not exceed 0.4 percent by weight of such polymers.

Substances	Limitations
Phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-*tert*-butylphenyl) ester (CAS Reg. No. 26741-53-7) which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122-20-3).	For use only at levels not to exceed 0.10 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, or 3.2, and limited to use in contact with food only under conditions of use B, C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter. Olefin polymers that contain more than 50 weight-percent of polymer units derived from ethylene shall have a density equal to or greater than 0.94 gram per cubic centimeter.
Phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-*tert*-butylphenyl)ester (CAS Reg. No. 26741-53-7).	For use only: 1. At levels not to exceed 0.86 percent by weight in polyvinyl chloride and/or vinyl chloride copolymers that comply with §§ 177.1950, 177.1960, 177.1970, or 177.1980 of this chapter for use with all food types described in Table 1 of § 176.170(c) of this chapter, except those containing more than 15 percent alcohol, under conditions of use B, C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.25 percent by weight of polycarbonate resins that comply with § 177.1580 of this chapter for use with all food types described in Table 1 of § 176.170(c) of this chapter, except those containing more than 15 percent alcohol, under conditions of use B, C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter.
Poly(1,4-cyclohexylenedimethylene-3,3'-thiodipropionate) partially terminated with stearyl alcohol and produced when approximately equal moles of 1,4-cyclohexanedimethanol and 3,3'-thiodipropionic acid are made to react in the presence of stearyl alcohol so that the final product has an average molecular weight in the range of 1,800-2,200, as determined by vapor pressure osmometry, and has a maximum acid value of 2.5.	For use only: 1. In polypropylene complying with § 177.1520(c) of this chapter, item 1.1, and used in contact with nonfatty, nonalcoholic food. 2. At levels not to exceed 0.5 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1, and used in contact with fatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact fatty nonalcoholic food shall not exceed 0.005 inch.
Poly[(1,3-dibutyldistannthianediylidene)-1,3-dithio] having the formula $[C_8H_{18}Sn_2S_3]_n$ (where *n* averages 1.5-2) and produced so as to meet the following specifications: Softening point, 130-145° C; volatile components at 150° C, less than 1.0 percent; sulphur (sulfide) content in the range 20.5-22.0 percent; tin content in the range 52.0-53.2 percent.	For use only at levels not to exceed 0.2 by percent weight in polyvinyl chloride resin where such resin constitutes not less than 98.7 percent of a finished semirigid or rigid polyvinyl chloride food-contact surface, provided that the finished food-contact article is employed only to package meat, cheese, and food Types I, VIII, and IX as described in Table 1 of § 176.170(c) of this chapter. The finished food-contact article containing this stabilizer, when extracted with refined cottonseed oil at 120° F for 48 hours, using a volume-to-surface ratio of 2 milliliters per square inch of surface tested, shall yield tin (Sn) not to exceed 0.0005 milligram per square inch of food-contact surface.
Poly[(6-morpholino-s-triazine-2,4-diyl)[(2,2,6,6-tetramethyl-4-piperidyl)imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]] (CAS Reg. No. 82451-48-7).	For use only: 1. At levels not to exceed 0.3 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3, and of ethylene polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.3, and 3.1, whose specific gravity is not less than 0.94. The finished polymers are to contact food only under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.3, and 3.1, whose specific gravity is less than 0.94, and of olefin polymers complying with items 3.3, 3.4, 3.5, and 4.0. The finished polymers are to contact food in articles having a volume of at least 18.9 liters (5 gallons) only under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.
Poly[[6-[(1,1,3,3-tetramethybutyl) amino]-*s*-triazine-2,4-diyl][2,2,6,6-tetramethyl-4-piperidyl)imino]hexa-methylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]] (CAS Reg. No. 70624-18-9).	For use only: 1. At levels not to exceed 0.3 percent by weight of polypropylene complying with § 177.1520 of this chapter. 2. At levels not to exceed 0.2 percent by weight of polyethylene complying with § 177.1520 of this chapter, that has a density equal to or greater than 0.94 gram per cubic centimeter.
Potassium bromide and either cupric acetate or cupric carbonate.	For use at levels not exceeding 0.18 percent potassium bromide and 0.005 percent copper as cupric acetate or cupric carbonate by weight of nylon 66 resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250° F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0015 inch.

Substances	Limitations
Stearoylbenzoylmethane (CAS Reg. No. 58446-52-9) consisting of a mixture of β-diketones produced by the condensation of acetophenone and technical methyl stearate..	For use only at levels not to exceed 0.5 percent by weight of vinyl chloride homopolymers modified in accordance with § 178.3790(b)(1). The finished polymers may be used in contact with food containing up to 50 percent alcohol under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
Tetrakis [methylene (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane (CAS Reg. No. 6683-19-8).	For use only: 1. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. 2. At levels not to exceed 0.05 percent by weight of ethylene-methacrylic acid copolymers complying with § 177.1330 of this chapter and ethylene-acrylic acid copolymers complying with § 177.1310 of this chapter. The average thickness of such copolymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not to exceed 0.5 percent by weight of the following polymers when used in articles that contact nonalcoholic food: Polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter; ethylene-acrylic acid copolymers complying with § 177.1310 of this chapter; ethylene-methacrylic acid copolymers, ethylene-methacrylic acid-vinyl acetate copolymers and their partial salts complying with § 177.1330 of this chapter; isobutylene polymers complying with § 177.1420 of this chapter; and styrene butadiene copolymers used in compliance with regulations in Parts 174, 175, 176, 177, 178, and § 179.45 of this chapter. 4. At levels not to exceed 1 percent by weight of polyoxymethylene copolymer as provided in § 177.2470(b)(1) of this chapter. 5. At levels not to exceed 0.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1) of this chapter. 6. At levels not to exceed 0.25 percent by weight of poly-1-butene resins and butene/ethylene copolymers complying with § 177.1570 of this chapter, except that when used in contact with foods described as Types III, IV-A, V, VII-A, and IX in Table 1 of § 176.170(c) of this chapter, the finished polymers may be used only under conditions of use C through H described in Table 2 of § 176.170(c) of this chapter. 7. At levels not to exceed 0.5 percent by weight of isobutylene polymers complying with § 177.1420 of this chapter, except that when such polymers are used in articles that contact alcoholic food, the use level shall not exceed 0.1 percent by weight. 8. In rubber articles intended for repeated use complying with § 177.2600 of this chapter, at levels not exceeding 0.5 percent by weight of the finished rubber product. 9. At levels not exceeding 0.1 percent by weight of olefin copolymers complying with item 3.4 in § 177.1520(c) of this chapter, provided that such copolymers are not modified with 5-ethylidine-2-norbornene, and/or 5-methylene-2-norbornene. 10. At levels not to exceed 0.5 percent by weight of ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter, except that when such polymers are used in articles that contact alcoholic food, the use level shall not exceed 0.2 percent by weight, and the articles may be used only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. 11. At levels not to exceed 0.5 percent by weight of ethylene phthalate polymers complying with § 177.1630 of this chapter. The finished food contact articles may be used under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. 12. At levels not to exceed 1 percent by weight of pressure sensitive adhesives complying with § 175.125 of this chapter. 13. At levels not to exceed 1 percent by weight of can end cement formulations complying with § 175.300(b)(3)(xxxi) of this chapter. 14. At levels not to exceed 1 percent by weight of petroleum alicyclic hydrocarbon resins complying with § 175.320(b)(3) of this chapter. 15. At levels not to exceed 1 percent by weight of petroleum alicyclic hydrocarbon resins or their hydrogenated products complying with § 176.170(b)(2) of this chapter. 16. At levels not to exceed 1 percent by weight of resins and polymers complying with § 176.180 of this chapter. 17. At levels not to exceed 1 percent by weight of rosin and rosin derivatives complying with § 176.210(d)(3) of this chapter. 18. At levels not to exceed 1 percent by weight of closures with sealing gaskets complying with § 177.1210 of this chapter. 19. At levels not to exceed 1 percent by weight of petroleum hydrocarbon resin and rosins and rosin derivatives complying with § 178.3800(b) of this chapter.

Substances	Limitations
	20. At levels not to exceed 1 percent by weight of reinforced wax complying with § 178.3850 of this chapter.
4,4-Thiobis(6-*tert*-butyl-*m*-cresol)	For use only: 1. As provided in §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.25 percent by weight of polyethylene complying with § 177.1520 of this chapter: *Provided*, That the specific gravity of the polyethylene is not less than 0.926: *And further provided*, That the finished polyethylene contacts food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, VI-B, and VIII.
Thiodipropionic acid	
1,3,5-Trimethyl-2,4,6-tris(3,5-di-*tert*-butyl-4-hydroxybenzyl) benzene.	For use only: 1. At levels not to exceed 0.5 percent by weight of polymers except nylon resins identified in § 177.1500 of this chapter. 2. At levels not to exceed 1 percent by weight of nylon resins identified in § 177.1500 of this chapter.
Tri(mixed mono-and dinonylphenyl) phosphite (which may contain not more than 1 percent by weight of triisopropanolamine).	
1,3,5-Tris(3,5-di-*tert*-butyl-4-hydroxyben-zyl)-*s*-triazine-2,4,6(1*H*,3*H*,5*H*)trione (CAS Reg. No. 27676–62–6).	For use only: 1. At levels not to exceed 0.25 percent by weight of polypropylene complying with § 177.1520 of this chapter. 2. In polyethylene complying with § 177.1520 of this chapter: (a) At levels not to exceed 0.1 weight percent. (b) At levels not to exceed 0.5 weight percent in contact with nonfatty food. 3. At levels not to exceed 0.5 percent by weight of ethylene-propylene-5-ethylidine-2-norbornene terpolymers complying with § 177.1520 of this chapter. The maximum thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 4. At levels not exceeding 0.1 percent by weight of olefin copolymers complying with §177.1520(c) of this chapter, items 3.1, 3.2, 3.3, 3.4, or 3.5.
1,3,5-Tris(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl) hexahydro-*s*-triazine.	For use only in contact with nonfatty foods: 1. At levels not to exceed 0.25 percent by weight of polypropylene complying with § 177.1520 of this chapter. 2. At levels not to exceed 0.1 percent by weight of polyethylene complying with § 177.1520 of this chapter. 3. At levels not to exceed 0.5 percent by weight of ethylene-propylene-5-ethylidine-2-norbornene terpolymers complying with § 177.1520 of this chapter. The maximum thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
1,3,5-Tris(4-*tert*-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione. [CAS Reg. No. 40601–76–1].	For use only: 1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520 of this chapter, under conditions of use A through H described in table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.1 percent by weight of polystyrene and rubber-modified polystyrene that comply with § 177.1640 of this chapter, provided that the finished polystyrene and rubber-modified polystyrene contact food only under the conditions described in § 176.170(c) of this chapter, Table 2, under conditions of use E through G.
Tris(2,4-di-*tert*-butylphenyl)phosphite. (CAS Reg. No. 31570–04–4).	For use only: 1. At levels not to exceed 0.5 percent by weight of elastomers used in rubber articles complying with § 177.2600 of this chapter. 2. At levels not to exceed 1 percent by weight of nylon resins complying with § 177.1500 of this chapter: *Provided*, That the finished polymer contacts food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 0.3 percent by weight of polycarbonate resins complying with § 177.1580 of this chapter. 4. At levels not to exceeds 0.2 percent by weight of polystyrene and rubber-modified polystyrene polymers complying with § 177.1640 of this chapter: *Provided*, that the finished polymer contacts food only under conditions of use B, C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter. 5. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, or 1.3.

Substances	Limitations
	6. At levels not to exceed 0.2. percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, 2.3, 3.1, or 3.2. The finished polymers complying with item 2.1, 2.2, or 2.3 having a density less than 0.94 gram per cubic centimeter and a thickness greater than 0.051 millimeter (0.002 inch), shall contact food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. 7. At levels not to exceed 0.2 percent by weight of ethylene-vinyl-acetate copolymers complying with § 177.1350 of this chapter, and that are limited to use in contact with food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. The average thickness of such polymers in the form in which they contact fatty food shall not exceed 0.1 millimeter (0.004 inch). 8. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 3.3 or 4. The finished polymers having a thickness greater than 0.051 millimeter (0.002 inch), shall contact food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. 9. At levels not to exceed 0.5 percent by weight of acrylic and modified acrylic plastics, semirigid and rigid, complying with § 177.1010 of this chapter. 10. At levels not to exceed 0.1 percent by weight of isobutylene polymers complying with § 177.1420 of this chapter. 11. In adhesives complying with § 175.105 of this chapter. 12. At levels not to exceed 0.5 percent by weight of pressure sensitive adhesives complying with § 175.125 of this chapter. 13. At levels not to exceed 0.5 percent by weight of can end cement formulations complying with § 175.300(b)(3) (xxxi) of this chapter. 14. At levels not to exceed 0.5 percent by weight of side seam cement formulations complying with § 175.300(b)(3) (xxxii) of this chapter. 15. At levels not to exceed 0.5 percent by weight of petroleum alicyclic hydrocarbon resins complying with § 175.320(b)(3) of this chapter. 16. At levels not to exceed 0.5 percent by weight of petroleum alicyclic hydrocarbon resins or their hydrogenated products complying with § 176.170(b) (2) of this chapter. 17. At levels not to exceed 0.5 percent by weight of resins and polymers complying with § 176.180(b) of this chapter. 18. At levels not to exceed 0.5 percent by weight of rosins and rosin derivatives complying with § 176.210(d)(3) of this chapter. 19. At levels not to exceed 0.5 percent by weight of closures with sealing gaskets complying with § 177.1210 of this chapter. 20. At levels not to exceed 0.5 percent by weight of petroleum hydrocarbon resin, and rosins and rosin derivatives complying with § 178.3800(b). 21. At levels not to exceed 0.5 percent by weight of reinforced wax complying with § 178.3850.
Tris(triethylene glycol) phosphate (CAS Reg. No. 9056-42-2).	At levels not to exceed 0.1 percent by weight of polyethylene phthalate polymers complying with § 177.1630 of this chapter, such that the polymers contact foods only of Type VI-B described in Table 1 of § 176.170(c) of this chapter.
Tris(2-methyl-4-hydroxy-5-*tert*-butylphenyl)butane (CAS Reg. No. 1843-03-4).	For use only: 1. At levels not to exceed 0.25 percent by weight of polymers used as provided in § 176.180 of this chapter. 2. At levels not to exceed 0.25 percent by weight of the following polymers when used in articles that contact food of Types I, II, IV-B, VI-B, VII-B, and VIII described in Table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. At levels not to exceed 0.1 percent by weight of the following polymers when used in articles that contact food of Types III, IV-A, V, VI-A, VI-C, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 4. As provided in § 175.105 of this chapter. 5. At levels not to exceed 0.2 percent by weight of polystyrene and/or modified polystyrene polymers identified in § 177.1640 of this chapter.

Substances	Limitations
	6. At levels not to exceed 0.25 percent by weight of acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods. 7. At levels not to exceed 1 percent by weight of closure-sealing gasket compositions complying with § 177.1210(b) of this chapter.
Zinc dibutyldithiocarbamate (CAS Reg. No. 136-23-2).	For use only: 1. At levels not to exceed 0.2 percent by weight of isobutylene-isoprene copolymers complying with § 177.1420 of this chapter: *Provided*, That the finished copolymers contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types V, VII, VIII, and IX. 2. At levels not to exceed 0.02 percent by weight of polypropylene polymers complying with § 177.1520(c), item 1.1 of this chapter.
Zinc palmitate	
Zinc salicylate	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: *Provided*, That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers.
Zinc stearate	

[1] Copies are available from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.

[42 FR 14609, Mar. 15, 1977]

Editorial Note: For additional Federal Register citations affecting § 178.2010, see the List of CFR Sections Affected in the Finding Aids section of this volume.

Effective Date Note: At 52 FR 6324, Mar. 3, 1987, § 178.2010(b) was amended in the entry "*N,N'*-Hexamethylenebis (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamamide)" by adding new entries 3, 4, and 5, effective April 2, 1987.

§ 178.2550 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

4-Hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used as an antioxidant in articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140°–141°C.

(b) The concentration of the additive and any other permitted antioxidants in the finished food-contact article does not exceed a total of 0.5 milligram per square inch of food-contact surface.

§ 178.2650 Organotin stabilizers in vinyl chloride plastics.

The organotin chemicals identified in paragraph (a) of this section may be safely used alone or in combination, at levels not to exceed a total of 3 parts per hundred of resin, as stabilizers in polyvinyl chloride and vinyl chloride copolymers complying with the provisions of § 177.1950 or § 177.1980 of this chapter and that are intended for use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, except for the octyltin chemical identified in paragraph (a)(3) of this section which may be used in contact with food of types I through IX at temperatures not exceeding 75 °C (167 °F), and further that the octyltin chemicals identified in paragraph (a)(5) and (6) of this section may be used in contact with food of types I through IX, at temperatures not exceeding 66 °C (150 °F), conditions of use D through G described in table 2 of § 176.170(c) of this chapter, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the octyltin chemicals are those identified in paragraph (a)(1), (2), (3), (4), (5), and (6) of this section.

(1) Di(*n*-octyl)tin S,S'-bis(iso-octylmer-captoacetate) is an octyltin chemical having 15.1 to 16.4 percent by weight of tin (Sn) and having 8.1 to 8.9 percent by weight of mercapto sulfur. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. Di(*n*-octyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of di(*n*-octyl)tin dichloride and not more than 5 percent by weight of tri(*n*-octyl)tin chloride. Di(*n*-octyl)tin oxide has an organotin composition that is not less than 95 percent by weight of di(*n*-

octyl)tin oxide and not more than 5 percent by weight of bis[tri(*n*-octyl)tin] oxide, and/or mono *n*-octyltin oxide.

(2) Di(*n*-octyl) tin maleate polymer is an octyltin chemical having the formula $[(C_8H_{17})_2SnC_4H_2O_4]_n$ (where n is between 2 and 4 inclusive), having 25.2 to 26.6 percent by weight of tin (Sn) and having a saponification number of 225 to 255. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide meeting the specifications prescribed for di(*n*- octyl) tin dichloride or di(*n*-octyl) tin oxide in paragraph (a)(1) of this section.

(3) C_{10-16}-Alkyl mercaptoacetates reaction products with dichlorodioctylstannane and trichlorooctylstannane (CAS Reg. No. 83447-69-2) is an organotin chemical mixture having 10.8 to 11.8 percent by weight of tin (Sn) and having 8.0 to 8.6 percent by weight of mercapto sulfur. It is made from a mixture of di(*n*-octyl)tin dichloride and (*n*-octyl)tin trichloride which has an organotin composition that is not less than 95 percent by weight di(*n*-octyl)tin dichloride/(*n*-octyl)tin trichloride, and not more than 1.5 percent by weight of tri(*n*-octyl)tin chloride. The alkyl radical in the mercaptoacetate is derived from a mixture of saturated *n*-alcohols which has a composition that is not less than 50 percent by weight tetradecyl alcohol, and that is not more than 50 percent by weight total of decyl alcohol and/or dodecyl alcohol, and/or hexadecyl alcohol.

(4) (*n*-Octyl)tin S,S'S" tris(isooctylmercaptoacetate) is an octyltin chemical having the formula n-$C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$ (CAS Reg. No. 26401-86-5) having 13.4 to 14.8 percent by weight of tin (Sn) and having 10.9 to 11.9 percent by weight of mercapto sulfur. It is made from (*n*-octyl)tin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. The (*n*-octyl)tin trichloride has an organotin composition that is not less than 95 percent by weight of (*n*-octyl)tin trichloride and not more than 5 percent by weight of tri(*n*-octyl)tin chloride.

(5) Bis(*beta*-carbobutoxyethyl)tin bis(isooctylmercaptoacetate) (CAS Reg. No. 63397-60-4) is an estertin chemical having 14.0 to 15.0 percent by weight of tin (Sn) and having 7.5 to 8.5 percent by weight of mercapto sulfur. It is made from bis(*beta*-carbobutoxyethyl)tin dichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols. The bis(*beta*-carbobutoxyethyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of bis(*beta*-carbobutoxyethyl)tin dichloride and not more than 5 percent by weight of bis(*beta*-carbobutoxyethyltin trichloride. The triestertin chloride content of bis(*beta*-carbobutoxyethyltin) dichloride shall not exceed 0.02 percent.

(6) *Beta*-carbobutoxyethyltin tris(isooctylmercaptoacetate) (CAS Reg. No. 63438-80-2) is an estertin chemical having 13.0 to 14.0 percent by weight of tin (Sn) and having 10.5 to 11.5 percent by weight of mercapto sulfur. It is made from *beta*-carbobutoxyethyltin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohol. The *beta*-carbobutoxyethyltin trichloride has an organotin composition that is not less than 95 percent by weight of *beta*-carbobutoxyethyltin trichloride and not more than 5 percent total of triestertin chloride and diestertin chloride.

(b) The vinyl chloride plastic containers, film or panels in the finished form in which they are to contact food, shall meet the following limitations:

(1) The finished plastics intended for contact with foods of the types listed in this section shall be extracted with the solvent or solvents characterizing those types of foods as determined from Table 2 of § 176.170(c) of this chapter at the temperature reflecting the conditions of intended use as determined therein. Additionally, extraction tests for acidic foods shall be included and simulated by 3-percent acetic acid at temperatures specified for water in Table 2 of § 176.170(c) of this chapter. The extraction tests shall cover at least three equilibrium periodic determinations, as follows:

(i) The exposure time for the first determination shall be at least 72 hours for aqueous solvents, and at least 6 hours for heptane.

(ii) Subsequent determinations shall be at a minimum of 24-hour intervals for aqueous solvents, and 2-hour intervals for heptane. These tests shall yield total octylin stabilizers not to exceed 0.5 parts per million as determined by analytical method entitled "Atomic Absorption Spectrometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry,* Vol. 49, p. 1090–1093 (1977), which is incorporated by reference.Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(2) In lieu of the tests prescribed in paragraph (b) (1) of this section, the finished plastics intended for contact with foods only of Types II, V, VI-A (except malt beverages), and VI-C may be end-tested with food-simulating solvents, under conditions of time and temperature, as specified below, whereby such tests shall yield the octyltin residues cited in paragraph (b)(1) of this section not in excess of 0.5 ppm:

	Food-simulating solvent	Time (hours)	Temperature (degrees Fahrenheit)
Type II	Acetic acid, 3 pct	48	135
Type V	Heptane	2	100
Type VI–A	Ethyl alcohol, 8 pct	24	120
Type VI–C	Ethyl alcohol, 50 percent.	24	120

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 48 FR 7170, Feb. 18, 1983; 48 FR 42972, Sept. 21, 1983; 48 FR 51612, Nov. 10, 1983; 49 FR 8432, Mar. 7, 1984; 50 FR 62, Jan. 2, 1985; 50 FR 3510, Jan. 25, 1985; 50 FR 37996, Sept. 19, 1985; 50 FR 47212, Nov. 15, 1985]

Subpart D—Certain Adjuvants and Production Aids

§ 178.3010 Adjuvant substances used in the manufacture of foamed plastics.

The following substances may be safely used as adjuvants in the manufacture of foamed plastics intended for use in contact with food, subject to any prescribed limitations:

List of substances	Limitations
Azodicarbonamide	For use as a blowing agent in polyethylene complying with item 2.1 in § 177.1520(c) of this chapter at a level not to exceed 5 percent by weight of finished foamed polyethylene.
Isopentane	For use as a blowing agent in polystyrene.
n-Pentane	Do.
1,1,2,2-Tetrachloroethylene	For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.3 percent by weight of finished foamed polystyrene intended for use in contact with food only of the types identified in § 176 170(c) of this chapter, Table 1, under Categories I, II, VI, and VIII.
Toluene	For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.35 percent by weight of finished foamed polystyrene.

[47 FR 22090, May 21, 1982]

§ 178.3120 Animal glue.

Animal glue may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Animal glue consists of the proteinaceous extractives obtained from hides, bones, and other collagen-rich substances of animal origin (excluding diseased or rotted animals), to which may be added other optional adjuvant substances required in its production or added to impart desired properties.

(b) The quantity of any substance employed in the production of animal glue does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitation further provided.

(c) Any substance employed in the production of animal glue and which is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Optional adjuvant substances employed in the production of animal glue include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in animal glue and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

List of substances	Limitations
Alum (double sulfate of aluminum and ammonium, potassium, or sodium).	
4-Chloro-3-methylphenol(*p*-chlorome-tacresol).	For use as preservative only.
Chromium potassium sulfate (chrome alum)	For use only in glue used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paper board.
3,5-Dimethyl-1,3,5,*H*-tetrahydrothiadia-zine-2-thione	For use as preservative only.
Disodium cyanodithioimidocarbonate	Do.
Defoaming agents	As provided in § 176.210 of this chapter.
Ethanolamine	
Ethylenediamine	
Formaldehyde	For use as a preservative only.
Potassium *N*-methyldithiocarbamate	Do.
Potassium pentachlorophenate	Do.
Rosins and rosin derivatives	As provided in § 178.3870.
Sodium chlorate	
Sodium dodecylbenzenesulfonate	
Sodium 2-mercaptobenzothiazole	For use as preservative only.
Sodium pentachlorophenate	Do.
Sodium *o*-phenylphenate	Do.
Zinc dimethyldithiocarbamate	Do.
Zinc 2-mercaptobenzothiazole	Do.

(e) The conditions of use are as follows:

(1) The use of animal glue in any substance or article that is the subject of a regulation in this subpart conforms with any specifications or limitations prescribed by such regulation for the finished form of the substance or article.

(2) It is used as an adhesive or component of an adhesive in accordance with the provisions of § 175.105 of this chapter.

(3) It is used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paperboard.

(4) It is used as a protective colloid in resinous and polymeric emulsion coatings.

§ 178.3125 Anticorrosive agents.

The substances listed in this section may be used as anticorrosive agents in food-contact materials subject to the provisions of this section:

Substances	Limitations
Zinc hydroxy phosphite (CAS Reg. No. 55799-16-1).	For use only as a component of resinous and polymeric food-contact coatings intended for repeated use in contact with dry foods.

[50 FR 21835, May 29, 1985]

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

The substances listed in paragraph (b) of this section may be safely used as antistatic and/or antifogging agents in food-packaging materials, subject to the provisions of this section:

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

List of substances	Limitations
Alpha-(Carboxymethyl)-omega-(tetradecyloxy)polyoxyethylene)	For use only as an antistatic and/or antifogging agent at levels not to exceed 0.2 pct by weight in polyolefin film not exceeding 0.001 inch thickness.
N-Acyl sarcosines where the acyl group is lauroyl, oleoyl, or derived from the combined fatty acids of coconut oil.	For use only: 1. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of polyolefin film used for packaging meat, fresh fruits, and fresh vegetables. The average thickness of such polyolefin film shall not exceed 0.003 inch. 2. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of ethylene-vinyl acetate copolymer film complying with § 177.1350 of this chapter and used for packaging meat, fresh fruits, fresh vegetables, and dry food of Type VIII described in Table 1 of § 176.170(c) of this chapter. The average thickness of such ethylene-vinyl acetate copolymer film shall not exceed 0.003 inch when used for packaging meat, fresh fruits, and fresh vegetables.
N,N-Bis(2-hydroxyethyl)alkyl(C_{12}–C_{18})amine	For use only as an antistatic agent at levels not to exceed 0.1 pct by weight of polyolefin food-contact films.
N,N-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups (C_{14}–C_{18}) are derived from tallow.	For use only: 1. As an antistatic agent at levels not to exceed 0.15 pct by weight in molded or extruded polyethylene containers that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types I, IV-B, VI-B, VII-B, and VIII, under the conditions of use E through G described in Table 2 of § 176.170(c) of this chapter provided such foods have a pH above 5.0. 2. As an antistatic agent at levels not to exceed 0.10 mg. per square inch of food-contact surface in vinylidene chloride copolymer coatings complying with § 175.320, § 177.1200, or § 177.1630 of this chapter, provided that such coatings contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types I, IV, VII, VIII, and IX under the conditions of use E through G described in Table 2 of § 176.170(c) of this chapter. The finished copolymers shall contain at least 70 weight pct of polymer units derived from vinylidene chloride; and shall contain not more than 5 weight pct of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.
N,N-Bis(2-hydroxyethyl) dodecanamide produced when diethanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36° C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free diethanolamine; and contains no more than 0.5 percent by weight of *N,N'*-bis(2-hydroxyethyl) piperazine, as determined by paper chromatography method.	For use only as an antistatic agent at levels not to exceed 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in Table 1 of § 176.170(c) of this chapter.
N,N-Bis(2-hydroxyethyl) octadecylamine, Chemical Abstracts Service Registry No. 10213-78-2, N-(2-hydroxyethyl)-*N*-octadecylglycine (monosodium salt), Chemical Abstracts Service Registry No. 66810-88-6, and *N,N*-Bis(2-hydroxyethyl)-*N*-(carboxymethyl) octadecanaminum hydroxide (inner salt), Chemical Abstracts Service Registry No. 24170-14-7, as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with sodium monochloroacetate and sodium hydroxide, such that the final product has: A nitrogen content of 3.3-3.8 percent; a melting point of 42°-50° C; and a pH of 10.0-11.5 in a 1 percent by weight aqueous solution.	For use only as an antistatic agent at levels not to exceed 0.45 percent by weight in polypropylene films complying with § 177.1520 of this chapter, and used for packaging food of Types I, II, III, IV, V, VI-B, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter, and under conditions of use B through H described in Table 2 of § 176.170(c). The average thickness of such polypropylene film shall not exceed 0.002 inch.
α-*n*-Dodecanol-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of *n*-dodecanol with an average of 9.5 moles of ethylene oxide to form a condensate having a hydroxyl content of 2.7 to 2.9 pct and having a cloud point of 80° C to 92° C in 1 pct by weight aqueous solution.	For use only as an antistatic agent at levels not to exceed 0.2 pct by weight in low-density polyethylene film having an average thickness not exceeding 0.005 inch.
Glycerol ester mixtures of ricinoleic acid, containing not more than 50 percent monoricinoleate, 45 pct diricinoleate, 10 pct triricinoleate, and 3.3 pct free glycerine.	As an antifogging agent at levels not exceeding 1.5 pct by weight of permitted plasticized vinyl chloride homo-and/or copolymers.

List of substances	Limitations
N-Methacryloyl ethyl-*N,N*-dimethylammonium-α-*N*-methyl carboxylate, octadecyl methacrylate, ethyl methacrylate, cyclohexyl methacrylate, *N*-vinyl-2-pyrrolidone copolymer. (CAS Reg. No. 64913-46-8).	For use only as an antistatic agent at levels not to exceed 0.2 percent by weight of polyolefin films that contact foods under the conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. The average thickness of such polyolefin film shall not exceed 0.02 centimeter (0.008 inch).
Octadecanoic acid 2-[2-hydroxyethyl) octadecylamino]ethyl ester (CAS Reg. No. 52497-24-2), (octadecylimino) diethylene distearate (CAS Reg. No. 94945-28-5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213-78-2), as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with octadecanoic acid, such that the final product has: a maximum acid value of 5 mg KOH/g and total amine value of 86 ±6 mg KOH/g as determined by a method entitled "Total Amine Value," which is incorporated by reference. Copies of the method are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408..	For use only as an antistatic agent at levels such that the product of film thickness in microns times the weight percent additive does not exceed 16, in polypropylene films complying with § 177.1520(c)1.1 of this chapter, and used for packaging food (except for food containing more than 8 percent alcohol) under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
Sodium *n*-alkylsulfonate (alkyl group in the range of C_{10}–C_{18} with not less than 50 percent C_{14}–C_{16}).	For use only as an antistatic agent at levels not to exceed 0.1 percent by weight of polyolefin films that comply with § 177.1520 of this chapter: *Provided*, That the finished olefin polymers contact foods of Types I, II, III, IV, V, VI-A, VI-B, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter, and under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.

[42 FR 14609, Mar. 15, 1977, as amended at 45 FR 56797, Aug. 26, 1980; 45 FR 85727, Dec. 30, 1980; 46 FR 13688, Feb. 24, 1981; 47 FR 26824, June 22, 1982; 51 FR 28932, Aug. 13, 1986]

§ 178.3280 Castor oil, hydrogenated.

Hydrogenated castor oil may be safely used in the manufacture of articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) The additive is used as follows:

Use	Limitations
1. As a lubricant for vinyl chloride polymers used in the manufacture of articles or components of articles authorized for food-contact use.	For use only at levels not to exceed 4 pct by weight of vinyl chloride polymers.
2. As a component of cellophane	Complying with § 177.1200 of this chapter.
3. As a component of resinous and polymeric coatings	Complying with § 175.300 of this chapter.
4. As a component of paper and paperboard in contact with aqueous and fatty food.	Complying with § 176.170 of this chapter.
5. As a component of closures with sealing gaskets for food containers.	Complying with § 177.1210 of this chapter.
6. As a component of cross-linked polyester resins	Complying with § 177.2420 of this chapter.

§ 178.3290 Chromic chloride complexes.

Myristo chromic chloride complex and stearato chromic chloride complex may be safely used as release agents in the closure area of packaging containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The quantity used shall not exceed that reasonably required to accomplish the intended technical effect nor exceed 7 micrograms of chromium per square inch of closure area.

(b) The packaging container which has its closure area treated with the release agent shall have a capacity of not less than 120 grams of food per square inch of such treated closure area.

§ 178.3295 Clarifying agents for polymers.

Clarifying agents may be safely used in polymers that are articles or components of articles intended for use in contact with food, subject to the provisions of this section:

Substances	Limitations
Dibenzylidene sorbitol (CAS Reg. No. 32647–67–9) formed by the condensation of two moles of benzaldehyde with one mole of sorbitol, such that the final product has a minimum content of 95 percent dibenzylidene sorbitol.	For use only as a clarifying agent for olefin polymers complying with § 177.1520(c) 1.1, 3.1, and 3.2 of this chapter under conditions of use C, D, E, F, and G, described in Table 2 of § 176.170(c) of this chapter at a level not exceeding 0.25 percent by weight of the polymer.

[46 FR 59236, Dec. 4, 1981]

§ 178.3297 Colorants for polymers.

The substances listed in paragraph (e) of this section may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions and definitions set forth in this section:

(a) The term "colorant" means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. For the purpose of this section, the term "colorant" includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material.

(b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.

(c) The colorant must conform to the specifications and extraction limits where indicated. Conformance to the extraction limits must be determined by established methods or their equivalent. Copies of the analytical methods and extraction procedures are available free of charge upon request from the Bureau of Foods, Division of Food and Color Additives (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. If the finished food-contact article is itself the subject of a regulation promulgated under section 409 of the act, it shall also comply with any specifications and limitations prescribed for it by that regulation.

(d) [Reserved]

(e) List of substances:

Substances	Limitations
1,1′-[(6-Phenyl-1,3,5-triazine-2,4-diyl)diimino]bis-9,10-anthracenedione (CAS Reg. No. 4118–16–5).	For use at levels not to exceed 0.25 percent by weight of polyethylene phthalate polymers that comply with § 177.1630 of this chapter. The finished articles are to contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter, except, when such articles are used with food types III, IV-A, and V, described in table 1, § 176.170(c) of this chapter, the finished articles are to contact food only under conditions of use D, E, F, and G.
2,2′-(2,5-Thiophenediyl)-bis (5-*tert*-butylbenzoxazole) (CAS Reg. No. 7128–64–5).	For use as an optical brightener only: 1. At levels not to exceed 0.05 percent by weight of the following polymers: olefin polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.3, 3.1, 3.3, or 4; polystyrene and rubbermodified polystyrene complying with § 177.1640 of this chapter; and polyvinyl chloride. The finished polymers shall contact foods only of the types identified in Table 1, § 176.170(c) of this chapter, under Categories I, II, IV–B, VI–A, VI–B, and VIII under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.05 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1, 1.2, or 1.3. The finished polymer shall contact foods only of the types identified in Table 1, § 176.170(c) of this chapter, under Categories I, II, IV–B, VI, VII–B, and VIII under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

Substances	Limitations
	3. At levels not to exceed 0.01 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1, 1.2, or 1.3. The finished polymer shall contact foods only of the types identified in Table 1, § 176.170(c) of this chapter, under Categories III, IV-A, V, VII-A, and IX under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.
Zinc sulfide	For use at levels not to exceed 10 percent by weight.

[48 FR 46774, 46775, Oct. 14, 1983, as amended at 51 FR 7551, Mar. 5, 1986; 51 FR 19168, May 28, 1986; 51 FR 23535, June 30, 1986]

§ 178.3300 Corrosion inhibitors used for steel or tinplate.

Corrosion inhibitors may be safely used for steel or tinplate intended for use in, or to be fabricated as, food containers or food-processing or handling equipment, subject to the provisions of this section.

(a) The corrosion inhibitors are prepared from substances identified in this section and used subject to the limitations prescribed.

(b) The following corrosion inhibitors or adjuvants are used in amounts not to exceed those reasonably required to accomplish the intended physical or technical effect:

(1) Corrosion inhibitors (active ingredients) used in packaging materials for the packaging of steel or tinplate or articles fabricated therefrom:

List of substances	Limitations
Dicyclohexylamine and its salts of fatty acids derived from animal or vegetable oil.	
Dicyclohexylamine nitrite	
Morpholine and its salts of fatty acids derived from animal or vegetable oils.	

(2) Adjuvants employed in the application and use of corrosion inhibitors:

List of substances	Limitations
Propylene glycol	

§ 178.3400 Emulsifiers and/or surface-active agents.

The substances listed in paragraph (c) of this section may be safely used as emulsifiers and/or surface-active agents in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect; and the quantity that may become a component of food as a result of such use shall not be intended to, nor in fact, accomplish any physical or technical effect in the food itself.

(b) The use as an emulsifier and/or surface active agent in any substance or article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) List of substances:

List of substances	Limitations
α-Alkyl-, α-alkenyl-, and α-alkylaryl-*omega*-hydroxypoly(oxyethylene) mixture consisting of 30 weight pct of α-(2,4,6-triisobutylphenyl)-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 7 moles and 70 weight pct of a 1:1 weight ratio mixture of α-(*Z*)-9-octadecenyl-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles and α-alkyl(C_{14}–C_{18})-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles.	For use only at levels not to exceed 0.5 pct by weight of coatings complying with § 175.320 of this chapter and limited to use as an emulsifier for polyhydric alcohol diesters used as provided in § 178.3770(b). The weight of the finished coating shall not exceed 2 milligrams per square inch of food-contact surface.

List of substances	Limitations
n-Alkylbenzenesulfonic acid (alkyl group consisting of not less than 95 percent C_{10} to C_{16}) and its ammonium, calcium, magnesium, potassium, and sodium salts.	For use only as emulsifiers and/or surface active agents as components of nonfood articles complying with §§ 175.300, 175.320, 175.365, 175.380, 176.170, 176.180, 177.1010, 177.1200, 177.1210, 177.1630, 177.2600, and 177.2800 of this chapter and § 178.3120.
α-Alkyl-*omega*-hydroxypoly(oxyethylene) produced by condensation of 1 mole of C_{11}–C_{15} straight-chain randomly substitued secondary alcohols with an average of 7–20 moles of ethylene oxide.	
n-Alkylsulfonate (alkyl group is in the range C_{10}–C_{18} with not less than 50 pct C_{14}–C_{16}).	For use only: 1. As provided in § 176.170 of this chapter. 2. At levels not to exceed 2 pct by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. As an emulsifier in vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contacts food only of the Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use E, F and G described in Table 2 of § 176.170 of this chapter.
alpha Olefin sulfonate [alkyl group is in the range of C_{10}–C_{18} with not less than 50 percent C_{14}–C_{16}], ammonium, calcium, magnesium, potassium, and sodium salts.	For use only: 1. In acrylonitrile-butadiene copolymers identified in § 177.2600(c)(4)(i) of this chapter. 2. At levels not to exceed 1 percent by weight of acrylic coatings complying with § 175.300(b)(3)(xx) of this chapter and having a maximum thickness of 0.051 millimeter (0.002 inch). The finished polymers contact food only of the Types V, VIII, and IX as identified in Table 1 of § 176.170(c) of this chapter. 3. At levels not to exceed 2 percent by weight of vinyl chloride copolymer coatings having a maximum thickness of 0.051 millimeter (0.002 inch) and complying with § 175.300(b)(3)(xv) of this chapter. The finished polymers contact food only of the Types V, VIII, and IX as identified in Table 1 of § 176.170(c) of this chapter. 4. As provided in § 175.105 of this chapter.
Alpha-sulfo-*omega*-(dodecyloxy)poly(oxyethylene) ammonium salt (CAS Reg. No. 30174–67–5).	For use only as an emulsifier at levels not to exceed 0.3 percent by weight of styrene-butadiene copolymer coatings for paper and paperboard complying with § 176.170 of this chapter.
Ammonium salt of epoxidized oleic acid, produced from epoxidized oleic acid (predominantly dihydroxystearic and acetoxyhydroxystearic acids) meeting the following specifications: Acid number 160–180, saponification number 210–235, iodine number 2–15, and epoxy groups 0–0.4 percent.	For use only: 1. As a polymerization emulsifier at levels not to exceed 1.5 pct by weight of vinyl chloride polymers used as components of nonfood articles complying with §§ 175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter. Such vinyl chloride polymers are limited to polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 2. As a polymerization emulsifier at levels not to exceed 1.5 pct by weight of vinyl chloride-vinyl acetate copolymers used as components of nonfood articles complying with §§ 175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter.
α-Di-*sec*-butylphenyl-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of di-*sec*-butylphenol with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50; *sec*-butyl groups are predominantly (90 percent or more) *o*-, *p*-substituents.	
α-Dodecyl-*omega*-hydroxpoly (oxyethylane) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 103–111 and that are produced by the esterification of the condensation product of 1 mole of *n*-dodecyl alcohol with 4–4.5 moles of ethylene oxide.	

List of substances	Limitations
α-(*p-Dodecylphenyl*)-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.	
α-(*p*-nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 49–59 and that are produced by the esterification of α-(*p*-nonylphenyl)-*omega*-hydroxypoly (oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 5.5–6.5 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 62–72 and that are produced by the esterification of α- (*p*-nonylphenyl) *omega*-hydroxypoly (oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 9–10 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 96–110 and that are produced by the esterification of α-(*p*-nonylphenyl)-*omega*-hydroxypoly (oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 45–55 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide: if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) sulfate, ammonium or sodium salt: the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content average 4 moles.	
Poly[(methylene-*p*-nonylphenoxy) poly(oxypropylene)](4–12 moles) propanol] of minimum molecular weight 3500.	For use in coatings at levels not to exceed 1 mg per square foot of food-contact surface.
Poly(oxypropylene) (45–48 moles) block polymer with poly(oxyethylene). The finished block polymers meet the following specifications: Average molecular weight 11,000–18,000; hydroxyl number 6.2–10.2; cloud point above 100° C. for 10 pct solution.	For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.
Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate) meeting the following specifications: Saponification number 40–50, acid number 0–2, hydroxyl number 60–108, oxyethylene content 70–74 pct.	
Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate) meeting the following specifications: Saponification number 41–52, oxyethylene content 66–70.5 pct.	
Polysorbate 60 conforming to the identity prescribed in § 172.836 of this chapter.	
Polysorbate 65 conforming to the identity prescribed in § 172.838 of this chapter.	
Polysorbate 80 conforming to the identity prescribed in § 172.840 of this chapter.	
Polysorbate 85 (polyoxyethylene (20) sorbitan trioleate) meeting the following specifications: Saponification number 80–95, oxyethylene content 46–50 percent.	
Sodium 1,4-dicyclohexyl sulfosuccinate	
Sodium 1,4-dihexyl sulfosuccinate	
Sodium 1,4 diisobutyl sulfosuccinate	
Sodium dioctyl sulfosuccinate	
Sodium 1,4-dipentyl sulfosuccinate	
Sodium 1,4-ditridecyl sulfosuccinate	
Sodium lauryl sulfate	

List of substances	Limitations
Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures containing not less than 70 pct of the monoalkylated product where the alkyl group is C_6-C_{16}.	
Sorbitan monolaurate meeting the following specifications. Saponification number 153–170; and hydroxyl number 330-380.	
Sorbitan monooleate meeting the following specifications: Saponification number 145–160, hydroxyl number 193–210.	
Sorbitan monopalmitate meeting the following specifications: Saponification No. 140–150; and hydroxyl No. 275–305.	
Sorbitan monostearate conforming to the identity prescribed in § 172.842 of this chapter.	
Sorbitan trioleate meeting the following specifications: Saponification No. 170–190; and hydroxyl No. 55–70.	
Sorbitan tristearate meeting the following specifications: Saponification No. 176–188; and hydroxyl No. 66–80.	
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl] *omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–40 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.	
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecyl-sulfosuccinate...	For use only as a polymerization emulsifier for resins applied to tea-bag material.
α-Tridecyl-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 75–85 and that are produced by the esterification of the condensation product of one mole of "oxo" process tridecyl alcohol with 5.5–6.5 moles of ethylene oxide.	
α-Tridecyl-*omega*-hydroxypoly (oxyethyl-ene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 58–70 and that are produced by the esterification of the condensation product of one mole of "oxo" process tridecyl alcohol with 9–10 moles of ethylene oxide.	

(d) The provisions of this section are not applicable to emulsifiers and/or surface-active agents listed in § 175.105(c)(5) of this chapter and used in food-packaging adhesives complying with § 175.105 of this chapter.

[42 FR 14609, Mar. 15, 1977, as amended at 43 FR 58557, Dec. 15, 1978; 44 FR 42679, July 20, 1979; 45 FR 67321, Oct. 10, 1980; 48 FR 24870, June 3, 1983; 49 FR 5748, Feb. 15, 1984; 51 FR 31763, Sept. 5, 1986]

§ 178.3450 Esters of stearic and palmitic acids.

The ester stearyl palmitate or palmityl stearate or mixtures thereof may be safely used as adjuvants in food-packaging materials when used in accordance with the following prescribed conditions:

(a) They are used or intended for use as plasticizers or lubricants in polystyrene intended for use in contact with food.

(b) They are added to the formulated polymer prior to extrusion.

(c) The quantity used shall not exceed that required to accomplish the intended technical effect.

§ 178.3480 Fatty alcohols, synthetic.

Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of 'articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The food additive consists of fatty alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except as provided in paragraph (c) of this section.

(b) It is used or intended for use as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted for use as components of articles intended for use in contact with food by existing regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter: *Provided*, That the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted for use as components of food-contact articles.

(c) Synthetic fatty alcohols identified in paragraph (c)(1) of this section may contain not more than 0.8 weight percent of total diols as determined by a method titled "Diols in Monohydroxy Alcohol by Miniature Thin Layer Chromatography (MTLC)," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(1) *Synthetic fatty alcohols.* (i) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except that they may contain not more than 0.8 weight percent total diols.

(ii) Lauryl, myristyl, cetyl, and stearyl alcohols manufactured by the process described in § 172.864(a)(2) of this chapter such that lauryl and myristyl alcohols meet the specifications in § 172.864(a)(1)(i) of this chapter, and cetyl and stearyl alcohols meet the specifications in § 172.864(a)(1)(ii) of this chapter.

(2) *Conditions of use.* (i) Synthetic fatty alcohols as substitutes for the corresponding naturally derived fatty alcohols permitted for use in compliance with § 178.3910.

(ii) Synthetic lauryl alcohol as a substitute for the naturally derived lauryl alcohol permitted as an intermediate in the synthesis of sodium lauryl sulfate used in compliance with § 178.3400.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982]

§ 178.3500 Glycerin, synthetic.

Synthetic glycerin may be safely used as a component of articles intended for use in packaging materials for food, subject to the provisions of this section:

(a) It is produced by the hydrogenolysis of carbohydrates, and shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used in a quantity not to exceed that amount reasonably required to produce its intended physical or technical effect, and in accordance with any limitations prescribed by applicable regulations in Parts 174, 175, 176, 177, 178 and 179 of this chapter. It shall not be intended to, nor in fact accomplish, any direct physical or technical effect in the food itself.

§ 178.3505 Glyceryl tri-(12-acetoxystearate).

Glyceryl tri-(12-acetoxystearate) (CAS Reg. No. 139-43-5) may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The additive is applied to the surface of calcium carbonate at a level not to exceed 1 weight-percent of the total mixture.

(b) The calcium carbonate/glyceryl tri-(12-acetoxystearate) mixture is used as an adjuvant in polymers in contact with nonfatty foods at a level not to exceed 20 weight-percent of the polymer.

[50 FR 1503, Jan. 11, 1985]

§ 178.3520 Industrial starch-modified.

Industrial starch-modified may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Industrial starch-modified is identified as follows:

(1) A food starch-modified or starch or any combination thereof that has

been modified by treatment with one of the reactants hereinafter specified, in an amount reasonably required to achieve the desired functional effect but in no event in excess of any limitation prescribed, with or without subsequent treatment as authorized in § 172.892 of this chapter.

List of reactants	Limitations
Ammonium persulfate, not to exceed 0.3 pct. or in alkaline starch not to exceed 0.6 pct..	
(4-Chlorobutene-2) trimethylammonium chloride, not to exceed 5 pct	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.
β-Diethylaminoethyl chloride hydrochloride, not to exceed 4 pct.	
Dimethylaminoethyl methacrylate, not to exceed 3 pct	
Dimethylol ethylene urea, not to exceed 0.375 pct	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.
2,3-Epoxypropyltrimethylammonium chloride, not to exceed 5 pct.	
Ethylene oxide, not to exceed 3 pct of reacted ethylene oxide in finished product.	
Phosphoric acid, not to exceed 6 pct and urea, not to exceed 20 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging and as surface sizing and coating for paper and paperboard that contact food only of Types IV-A, V, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter.

(2) A starch irradiated under one of the following conditions to produce free radicals for subsequent graft polymerization with the reactants listed in this paragraph (a)(2):

(i) Radiation from a sealed cobalt 60 source, maximum absorbed dose not to exceed 5.0 megarads.

(ii) An electron beam source at a maximum energy of 7 million electron volts of ionizing radiation, maximum absorbed dose not to exceed 5.0 megarads.

List of reactants	Limitations
Acrylamide and [2-(methacryloyloxy) ethyl]trimethylammonium methyl sulfate, such that the finished industrial starch-modified shall contain: 1. Not more than 60 weight percent vinyl copolymer (of which not more than 32 weight percent is [2-(methacryloyloxy)ethyl] trimethylammonium methyl sulfate). 2. Not more than 0.20 pct residual acrylamide 3. A minimum nitrogen content of 9.0 pct	For use only as a retention aid and dry strength agent employed before the sheet-forming operation in the manufacture of paper and paperboard intended to contact food, and used at a level not to exceed 0.25 pct by weight of the finished dry paper and paperboard fibers.

(b) The following adjuvants may be used as surface-active agents in the processing of industrial starch-modified:

Polyethylene glycol (400) dilaurate.
Polyethylene glycol (400) monolaurate.
Polyoxyethylene (4) lauryl ether.

(c) To insure safe use of the industrial starch-modified, the label of the food additive container shall bear the name of the additive "industrial starch-modified," and in the instance of an industrial starch-modified which is limited with respect to conditions of use, the label of the food additive container shall contain a statement of such limited use.

[42 FR 14609, Mar. 15, 1977, as amended at 42 FR 49453, Sept. 27, 1977]

§ 178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.

Isoparaffinic petroleum hydrocarbons, synthetic, may be safely used in the production of nonfood articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The isoparaffinic petroleum hydrocarbons, produced by synthesis from petroleum gases consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 63° -260° C, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Ultraviolet absorbance:

280-319 millimicrons—1.5 maximum.
320-329 millimicrons—0.08 maximum.
330-350 millimicrons—0.05 maximum.

Nonvolatile residue 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specifications" on page 66 of the *Journal of the Association of Official Agricultural Chemists*, Vol. 45 (February 1962), which is incorporated by reference, disregarding the last sentence of that procedure. For hydrocarbons boiling below 121° C, the nonvolatile residue shall be determined by ASTM method D1353-78, "Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;" for those boiling above 121° C, ASTM procedure D381-80, "Standard Test Method for Existent Gum in Fuels by Jet Evaporation," which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect.

(c) Isoparaffinic petroleum hydrocarbons are used in the production of nonfood articles. The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect, and the residual remaining in the finished article shall be the minimum amount reasonably attainable.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984]

§ 178.3550 Kaolin-modified.

Kaolin-modified, as identified in this section, may be safely used in olefin polymers as articles or components of articles intended for use in contact with food, subject to the provisions of this section.

(a) Kaolin-modified is produced by treating kaolin with a reaction product of isopropyl titanate and oleic acid in which 1 mole of isopropyl titanate is reacted with 1 to 2 moles of oleic acid. The reaction product will not exceed 8 percent of the modified kaolin. The oleic acid used shall meet the requirements specified in § 172.860 of this chapter.

(b) The additive is used as a pigment, colorant, or opacifier in olefin polymers complying with § 177.1520 of this chapter at levels not to exceed 40 percent by weight of the olefin polymer.

§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

(1) Substances generally recognized as safe for use in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances identified in this paragraph (a)(3).

Substances	Limitations
Aluminum stearoyl benzoyl hydroxide	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil.
BHA	
BHT	
α-Butyl-*omega*-hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.	Addition to food not to exceed 10 parts per million.
α-Butyl-*omega*-hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.	Do.
Castor oil	Do.
Castor oil, dehydrated	Do.
Castor oil, partially dehydrated	Do.
Dialkyldimethylammonium aluminum silicate where the alkyl groups are derived from hydrogenated tallow fatty acids (C_{14}-C_{18}) and where the aluminum silicate is derived from bentonite.	For use only as a gelling agent in mineral oil lubricants at a level not to exceed 7 pct by weight of the mineral oil.
Dimethylpolysiloxane (viscosity greater than 300 centistokes)	Addition to food not to exceed 1 part per million.
Disodium EDTA (CAS Reg. No. 139-33-3)	For use only as a chelating agent and sequestrant at a level not to exceed 0.06 percent by weight of lubricant at final use dilution.
Ethoxylated resin phosphate ester mixture consisting of the following compounds: 1. Poly(methylene-*p-tert*-butyl- phenoxy)poly-(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of *p-tert*-butylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; 2. Poly(methylene-*p*-nonylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of *p*-nonylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; and 3. *n*-Tridecyl alcohol mixture of dihydrogen phosphate and monohydrogen phosphate esters (40 to 80 percent of the mixture; CAS Reg. No. 56831-62-0).	For use only as a surfactant to improve lubricity in lubricating fluids complying with this section at a level not to exceed 5 percent by weight of the lubricating fluid.
Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.	
Hexamethylenebis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
α-Hydro-*omega*-hydroxypoly (oxyethylene) poly(oxypropylene) produced by random condensation of mixtures of ethylene oxide and propylene oxide containing 25 to 75 percent by weight of ethylene oxide; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-11-6.	Addition to food not to exceed 10 parts per million.
12-Hydroxystearic acid	
Isopropyl oleate	For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.
Magnesium ricinoleate	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Mineral oil	Addition to food not to exceed 10 parts per million.
Petrolatum	Complying with § 178.3700. Addition to food not to exceed 10 parts per million.
Phenyl-α-and/or phenyl-β-naphthylamine	For use only, singly or in combination, as antioxidant in mineral oil lubricants at a level not to exceed a total of 1 percent by weight of the mineral oil.
Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14} alkylamines.	For use only as an adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Phosphoric acid, mono- and diisooctyl esters, reacted with *tert*-alkyl and (C_{11}-C_{14}) primary amines (CAS Reg. No. 68187-67-7).	For use only as a corrosion inhibitor or rust preventative inlubricants at a level not to exceed 0.5 percent by weight of the lubricant.
Polyurea, having a nitrogen content of 9-14 percent based on the dry polyurea weight, produced by reacting tolylene diisocyanate with tall oil fatty acid (C_{16} and C_{18}) amine and ethylene diamine in a 2:2:1 molar ratio.	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Polybutene (minimum average molecular weight 80,000)	Addition to food not to exceed 10 parts per million.

Substances	Limitations
Polybutene, hydrogenated, complying with the identity prescribed under § 178.3740	Do.
Polyethylene	Do.
Polyisobutylene (average molecular weight 35,000-140,000 (Flory))	For use only as a thickening agent in mineral oil lubricants.
Sodium nitrite	For use only as a rust preventive in mineral oil lubricants at a level not to exceed 3 percent by weight of the mineral oil.
Tetrakis[methylene(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)]methane (CAS Reg. No. 6683-19-8)	For use only as an antioxidant in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 41484-35-9)	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Triphenyl phosphorothionate (CAS Reg. No. 597-82-0)	For use as an adjuvant in lubricants herein listed at a level not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis(3,5-di-*tert*-butyl-4-hydroxy-hydro- cinnamate) (CAS Reg. No. 41484-35-9)	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Zinc sulfide	For use at levels not to exceed 10 percent by weight of the lubricant.

(b) The lubricants are used on food-processing equipment as a protective antirust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed.

(c) Any substance employed in the production of the lubricants described in this section that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

[42 FR 14609, Mar. 15, 1977, as amended at 43 FR 54928, Nov. 24, 1978; 47 FR 41105, Sept. 17, 1982; 47 FR 46078, Oct. 15, 1982; 47 FR 51108, Nov. 12, 1982; 47 FR 53347, Nov. 26, 1982; 47 FR 57692, Dec. 28, 1982; 48 FR 2751, Jan. 21, 1983; 48 FR 8445, Mar. 1, 1983; 48 FR 9246, Mar. 4, 1983; 50 FR 50612, Dec. 11, 1985; 51 FR 7552, Mar. 5, 1986]

§ 178.3600 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester identified in § 172.816(a) of this chapter may be safely used as a processing aid (filter aid) in the manufacture of starch, including industrial starch-modified complying with § 178.3520, intended for use as a component of articles that contact food.

§ 178.3610 *α*-Methylstyrene-vinyltoluene resins, hydrogenated.

Hydrogenated *α*-methylstyrene-vinyltoluene copolymer resins having a molar ratio of 1 *α*-methylstyrene to 3 vinyltoluene may be safely used as components of polyolefin film intended for use in contact with food, subject to the following provisions:

(a) Hydrogenated *α*-methylstyrene-vinyltoluene copolymer resins have a drop-softening point of 125° to 165° C and a maximum absorptivity of 0.17 liter per gram centimeter at 266 nanometers, as determined by methods titled "Determination of Softening Point (Drop Method)" and "Determination of Unsaturation of Resin 1977," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) The polyolefin film is produced from olefin polymers complying with § 177.1520 of this chapter, and the average thickness of the film in the form in which it contacts food does not exceed 0.002 inch.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982]

§ 178.3620 Mineral oil.

Mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, subject to the provisions of this section:

(a) White mineral oil meeting the specifications prescribed in § 172.878 of this chapter may be used as a component of nonfood articles provided such use complies with any applicable limitations in Parts 170 through 189 of this chapter. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of § 172.878 of this chapter.

(b) Technical white mineral oil identified in paragraph (b)(1) of this section may be used as provided in paragraph (b)(2) of this section.

(1) Technical white mineral oil consists of specially refined distillates of virgin petroleum or of specially refined distillates that are produced synthetically from petroleum gases. Technical white mineral oil meets the following specifications:

(i) Saybolt color 20 minimum as determined by ASTM method D156-82, "Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 350	0.8

Technical white mineral oil containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specification" on page 66 of the *Journal of the Association of Official Agricultural Chemists*, Volume 45 (February 1962) (which is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), disregarding the last two sentences of that procedure and substituting therefor the following: Determine the absorbance of the mineral oil extract in a 10-millimeter cell in the range from 260-350 mμ, inclusive, compared to the solvent control. If the absorbance so measured exceeds 2.0 at any point in range 280-350 mμ, inclusive, dilute the extract and the solvent control, respectively, to twice their volume with dimethyl sulfoxide and remeasure the absorbance. Multiply the remeasured absorbance values by 2 to determine the absorbance of the mineral oil extract per centimeter optical pathlength.

(2) Technical white mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105, 176.200, 176.210, 177.2260, 177.2600, and 177.2800 of this chapter and §§ 178.3570 and 178.3910.

(3) Technical white mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) Mineral oil identified in paragraph (c)(1) of this section may be used as provided in paragraph (c)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Initial boiling point of 450°F minimum.

(ii) Color 5.5 maximum as determined by ASTM method D1500-82, "Standard Test Method for ASTM Color of Petroleum Products (ASTM Color Scale)," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(iii) Ultraviolet absorbance limits as follows as determined by the analytical method described in paragraph (c)(3) of this section:

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	0.7
290 to 299	0.6
300 to 359	0.4
360 to 400	09

(2) The mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105 and 176.210 of this chapter and § 178.3910 (for use only in rolling of metallic foil and sheet stock), §§ 176.200, 177.2260, 177.2600, and 177.2800 of this chapter.

(3) The analytical method for determining ultraviolet absorbance limit is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ±0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disk approximately $\frac{3}{16}$-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeter ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy[1] ±0.05 at 0.4 absorbance.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

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[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. *10 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. *20 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

3. *Acetone-benzene-water mixture.* Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

n-Hexadecane, 99-percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 mμ-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corporation, Camas, Washington, or equivalent). Absorbance (1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength	Absorbance (maximum)
261.5	1.00
270	.20
275	.09
280	.06
300	.015

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the adsorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the adsorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the adsorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160° C ± 1° C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized adsorbent between 60-180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns Mansville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60-180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160° C±1° C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter course, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 mμ and 400 mμ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without an oil sample, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter pathlength following the extraction stage should not exceed 0.02 in the wavelength range from 280 mμ to 400 mμ; the absorbance per centimeter pathlength following the complete procedure should not exceed 0.02 in the wavelength range from 280 mμ to 400 mμ. If in either spectrum the characteristic benzene peaks in the 250 mμ-260 mμ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Weigh a 20-gram sample of the oil and transfer to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of preequilibrated isooctane to give a total volume of the oil and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 280 mμ-400 mμ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without an oil sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the oil meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter pathlength exceeds the limits prescribed in this paragraph, proceed as follows: Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint, and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2-3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 2-3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (Caution: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2-3 milliliters per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to eluate the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate pre-washed with benzene (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic solvents." Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 250 mμ-400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without an oil sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ-260 mμ region, evaporate the solution to remove benzene by the procedure under "Organic solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 200-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits proposed in this paragraph, the oil meets the proposed ultraviolet absorbance specifications.

(d) Mineral oil identified in paragraph (d)(1) of this section may be used as provided in paragraph (d)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Distillation endpoint at 760 millimeters pressure not to exceed 371° C, with a maximum residue not to exceed 2 percent, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(ii) Ultraviolet absorbance limits as follows as determined by the method described in paragraph (d)(3) of this section.

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 299	2.3
300 to 319	1.2
320 to 359	.8
360 to 400	.3

(iii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(2) The mineral oil may be used only in the processing of jute fiber employed in the production of textile bags intended for use in contact with the following types of food: Dry grains and dry seeds (for example, beans, peas, rice, and lentils); whole root crop vegetables of the types identified in 40 CFR 180.34(f); unshelled and shelled nuts (including peanuts); and dry animal feed. The finished processed jute fiber shall contain no more than 6 percent by weight of residual mineral oil.

(3) The analytical method for determining ultraviolet absorbance limits and pyrene content is as follows:

I. *Apparatus.* A. Assorted beakers, separatory funnels fitted with tetrafluoroethylene polymer stopcocks, and graduated cylinders.

B. Volumetric flasks, 200-milliliter.

C. A chromatographic column made from nominal 1.3 centimeters outside diameter x 75 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I.E below.

D. A chromatographic column made from nominal 1.7 centimeters outside diameter x 115 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a 2.5 centimeters outside diameter x 9.0 centimeters glass tube having a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I. E below.

E. A 500-milliliter reservoir having a 24/40 standard taper male fitting at bottom and a suitable ball joint at the top for connecting to the nitrogen supply. The female fitting of the chromatographic columns described in items I. C and D above and the male fitting of the reservoir described in this item E should both be equipped with glass hooks.

(NOTE: Rubber stoppers are not to be used. Stopcock grease is not to be used on ground-glass joints in this method.)

F. A spectrophotometer equipped to automatically record absorbance of liquid samples in 1-centimeter pathlength cells in the spectral region of 280-400 mμ with a spectral slit width of 2 mμ or less. At an absorbance level of about 0.4, absorbance measurements shall be repeatable within ±0.01 and accurate within ±0.05. Wavelength measurements shall be repeatable with ±0.2 mμ and accurate within ±1.0 mμ. Instrument operating conditions are selected to realize this performance under dynamic (automatic) recording operations. Accuracy of absorbance measurements are determined at 290, 345, and 400 mμ, using potassium chromate as the reference standard. (National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949.)

G. Two fused quartz cells having pathlengths of 1.00±0.005 centimeter or better.

II. *Purity of reagents and materials.* Reagent-grade chemicals shall be used in all tests. It is further specified that each chemical shall be tested for purity in accordance with the instruction given under "Reagents and Materials" in III below. In addition, a blank run by the procedure shall be made on each purified lot of reagents and materials. Unless otherwise indicated, references to water shall be understood to mean distilled water.

III. *Reagents and materials*—A. *Organic solvents.* All solvents used throughout the procedure shall meet the specifications and tests described in this section III. The isooctane, benzene, cyclohexane, nitromethane, and *n*-hexadecane designated shall pass the following test: To the specified quantity of solvent in a 150-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains (to the residue from benzene and nitromethane add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of solvent). Dissolve the 1 milliliter of *n*-hexadecane residue in isooctane and make to 10-milliliter volume. Determine the absorbance in 1.0-centimeter pathlength cells compared to water as reference. The absorbance of the solution of solvent residue shall not exceed 0.05 between 280 and 400 mμ.

1. *Isooctane (2,2,4-trimethylpentane).* Use 240 milliliters for the above test. Purify, if necessary, by passage through a column of activated silica gel.

2. *Benzene.* Use 200 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

3. *Cyclohexane.* Use 70 milliliters for the above test. Purify, if necessary, by distillation, silica gel percolation, or otherwise.

4. *Nitromethane.* Use 125 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

5. *n-Hexadecane.* Determine the absorbance on this solvent directly. Purify, if necessary, by silica gel percolation or otherwise.

B. *Other materials*—1. *Pyrene standard reference.* Pyrene, reagent grade, melting point range 150-152° C. (Organic Chemical 3627, Eastman Kodak Co., Rochester, N.Y., or equivalent). The standard reference absorbance is the absorbance at 334 millimicrons of a standard reference solution of pyrene containing a concentration of 1.0 milligram per liter in purified isooctane measured against isooctane of the same spectral purity in 1.0-centimeter cells. (This absorbance will be approximately 0.28.)

2. *Chrysene solution.* Prepare a solution at a concentration of 5.0 milligrams per liter by dissolving 5.0 milligrams of chrysene in purified isooctane in a 1-liter volumetric flask. Adjust to volume with isooctane.

3. *Nitrogen gas.* Water pumped or equivalent purity, cylinder with regulator, and valve control flow at 5 p.s.i.

4. *Silica gel.* 100-200 mesh (Davison Chemical, Baltimore, Md., Grade 923, or equivalent), purified and activated by the following procedure: Place about 1 kilogram of silica gel in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. When the silica gel has been sufficiently cleaned, activate the gel before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth and heating in an oven (Caution! Explosion Hazard) at 130° C. for 16 hours, and store in a vacuum desiccator. Reheating about once a week is necessary if the silica gel is repeatedly removed from the desiccator.

5. *Aluminum oxide (Aluminum Co. of America, Grade F-20, or equivalent grade).* 80-200 mesh, purified and activated by the following procedure: Place about 1 kilogram of aluminum oxide in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. (Caution! Remove Benzene From Adsorbent Under Vacuum To Minimize Explosion Hazard in Subsequent Heating!) When the aluminum oxide has been sufficiently cleaned and freed of solvent, activate it before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth. Heat in an oven at 130° C for 16 hours. Upon removal from heat, store at atmospheric pressure over 80 percent (by weight) sulfuric acid in a desiccator for at least 36 hours before use. This gives aluminum oxide with between 6 to 9.5 percent volatiles. This is determined by heating a weighed sample of the prepared aluminum oxide at 2,000° F for 2 hours and then quickly reweighing. To insure the proper adsorptive properties of the aluminum oxide, perform the following test:

a. Weigh 50 grams ±1 gram of the activated aluminum oxide and pack into the chromatographic column (1.3 centimeters x 75 centimeters) described under "Apparatus" in C under I above. Use glass wool at the column exit to prevent the aluminum oxide from passing through the column.

b. Place a 250-milliliter graduated cylinder under the column to measure the amount of eluate coming from the column.

c. Prewet the aluminum oxide by passing 40 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 1.5 to 2.5 milliliters per minute.

d. Just prior to the last of the isooctane reaching the top of the aluminum oxide bed, add 10 milliliters of the isooctane solution containing 5.0 milligrams of chrysene per liter.

e. Continue percolation until the isooctane is just above the aluminum oxide. Then add 200 milliliters of a mixture of benzene and isooctane (33⅓ percent benzene and 66⅔ percent isooctane by volume) to the reservoir and continue percolation.

f. Continue percolation, collecting the eluates (40 milliliters of the prewet solution, 10 milliliters of the sample solution, and 200 milliliters of the gradient solution) in the 250-milliliter graduated cylinder until the level of the gradient solution is just above the aluminum oxide. Add 200 milliliters of the eluting solution of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume) to the column and continue collecting until a total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

g. Place a 100-milliliter graduated cylinder under the column and continue the percolation until a 100-milliliter eluate has been obtained.

h. Measure the amount of chrysene in this 100-milliliter fraction by ultraviolet analysis. If the aluminum oxide is satisfactory, more than 80 percent of the original amount of chrysene should be found in this fraction. (NOTE: If the amount of chrysene recovered is less than 80 percent, the original batch of aluminum oxide should be sieved between 100-160 mesh. Activation and testing of this sieved batch should indicate a satisfactory aluminum oxide for use.)

IV. *Sampling.* Precautions must be taken to insure that an uncontaminated sample of the mineral oil is obtained since ultraviolet absorption is very sensitive to small amounts of extraneous material contaminating the sample through careless handling.

V. *Procedure. A. Blank.* Before proceeding with the analysis of a sample, determine the absorbance of the solvent residues by carrying out the procedure without a sample.

B. *Sample.* 1. Weigh out 20.0 grams ±0.1 gram of the mineral oil into a beaker and transfer to a 250-milliliter separatory funnel fitted with a tetrafluoroethylene polymer stopcock, using enough cyclohexane (25 milliliters) to give a final total volume of 50 milliliters (mineral oil plus cyclohexane).

2. Add 25 milliliters of nitromethane saturated with cyclohexane and shake by hand vigorously for 3 minutes. Recover the lower nitromethane layer in a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Repeat the extraction four more times, recovering each extract in the 150-milliliter beaker. Exercise care not to fill the beaker to such a capacity that solvent losses may occur. Evaporate the combined nitromethane extracts to 1 milliliter of *n*-hexadecane residue containing the nitromethane-soluble mineral oil extractives. (NOTE: Complete removal of the nitromethane is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

3. Remove the beaker from the steam bath and allow to cool.

4. Weigh 50 grams ±1 gram of activated aluminum oxide and pack into the chromatographic column (1.3 centimeters x 75 centimeters) described under "Apparatus" in C under I above. (NOTE: A small plug of glass wool is placed at the column exit to prevent the aluminum oxide from passing through the column. After adding aluminum oxide, tap the column lightly to remove air voids. All percolations using aluminum oxide are performed under nitrogen pressure. The 500-milliliter reservoir described under "Apparatus" in E under I above is to be used to hold the elution solvents.)

5. Prewet the column by adding 40 milliliters of isooctane to the column. Adjust nitrogen pressure so that rate of descent of the isooctane coming off the column is 2.0 to 3.0 milliliters per minute. Be careful to maintain the level of solvent in the reservoir to prevent air from entering the aluminum oxide bed. New or additional solvent is added just before the last portion of the previous solvent enters the bed. To minimize possible photo-oxidation effects, the following procedures (steps 6 through 18) shall be carried out in subdued light.

6. Before the last of the isooctane reaches the top of the aluminum oxide bed, release the nitrogen pressure and turn off the stopcock on the column. Transfer the *n*-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10-15 milliliters).

7. Open the stopcock and continue percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

8. Just before the isooctane surface reaches the top of the aluminum oxide bed, add 200 milliliters of a mixture of benzene and isooctane (33⅓ percent benzene and 66⅔ percent isooctane by volume) to the reservoir, and continue the percolation.

9. Just before the surface of this mixture reaches the top of the aluminum oxide bed, release the nitrogen pressure, turn off the stopcock, and discard all the elution solvents collected up to this point.

10. Add to the reservoir 300 milliliters of a mixture of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume), place a 25-milliliter graduated cylinder under the column, continue the percolation until 20 milliliters of eluate has been collected, and then discard the eluate.

11. At this point, place a clean 250-milliliter Erlenmeyer flask under the column. Continue the percolation and collect all the remaining eluate.

(NOTE: Allow the column to drain completely. An increase in the nitrogen pressure may be necessary as the last of the solvent comes off the column.)

12. Place 1 milliliter of *n*-hexadecane into a 150-milliliter beaker. Place this onto a steam bath under a nitrogen stream and transfer in small portions the eluate from step 11 above. Wash out the Erlenmeyer flask with small amounts of benzene and transfer to the evaporation beaker. Evaporate until only 1 milliliter of hexadecane

residue remains. (NOTE: Complete removal of the benzene is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

13. Remove the beaker from the steam bath and cool.

14. Place a sample of 113.5 grams activated 100- 200-mesh silica gel in a 500-milliliter glass-stoppered Erlenmeyer flask. Add to the silica gel 46.2 grams (41 milliliters) of nitromethane. Stopper and shake the flask vigorously until no lumps of silica gel are observed and then shake occasionally during a period of 1 hour. The resultant nitromethane-treated silica gel is 29 weight-percent nitro-methane and 71 weight-percent silica gel.

15. Place a small plug of glass wool in the tapered end of the 1.7 centimeters outside diameter x 115 centimeters column, described under "Apparatus" in D of I above, adjacent to the stopcock to prevent silica gel from passing through the stopcock. Pack the nitromethane-treated silica gel into the column, tapping lightly. The resultant silica gel bed should be about 95 centimeters in depth. Place into a flask 170 milliliters of isooctane saturated with nitromethane.

16. Place a 100-milliliter graduated cylinder under the column and transfer the residue from the beaker in procedure step 13 above with several washes of the 170 milliliters of isooctane, saturated with nitromethane, onto the top of the column. (Total volume of washes should be no greater than 10 to 15 milliliters.) Permit isooctane solution to enter the silica gel bed until the liquid level is at the top bed level. Place the remaining amount of the 170 milliliters of isooctane, saturated with nitromethane, in the reservoir above the bed for percolation through the silica gel. Apply nitrogen pressure to the top of the column, adjusting the pressure so that the isooctane is collected at the rate of 2.5 to 3.5 milliliters per minute, and percolate isooctane through the bed until a quantity of 75.0 milliliters of eluate is collected. Discard the 75 milliliters of eluate. Turn off the stopcock and add 250 milliliters of benzene to the reservoir above the bed. Use a 400-milliliter beaker to collect the remaining eluate.

17. Open the stopcock, renew the pressure, and percolate the remaining isooctane and benzene through the column eluting the remaining aromatics. Transfer the eluate in small portions from the 400 milliliter beaker to a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Rinse the 400-milliliter beaker well with small portions of isooctane to obtain a complete transfer.

(NOTE: Complete removal of the nitromethane and benzene is essential. This can be assured by successive additions of 5 milliliters of isooctane and reevaporation.)

18. Transfer the residue with several washes of isooctane into a 200-milliliter volumetric flask. Add isooctane to mark.

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 mμ. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (mμ), 280-299, 300-319, 320-359, 360-400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 mμ, the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 m) by the base-line technique described in ASTM method E169-63 (Reapproved 1981), "Standard Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Correct each of the maximum absorbances in the respective specified wavelength intervals by subtracting the absorbance due to pyrene, determined as follows:

Absorbance due to pyrene =

$$\frac{Cp \times Sa}{Sp}$$

Where:

Cp = Calculated concentration of pyrene in sample solution;

Sp = Concentration of pyrene reference standard solution in same units of concentration;

Sa = Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

Pyrene content (p.p.m.) =

$$\frac{(200/1000) \times C}{20/1000} = 10C$$

Where:

C = Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 mμ, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984]

§ 178.3650 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used, as a component of nonfood articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

(1) Odor is faint and not kerosenic.

(2) Initial boiling point is 300° F minimum.

(3) Final boiling point is 650° F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii), as follows:

Wavelength (Mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 360	.8

(c) The additive is used as follows:

Use	Limitations
As a plasticizer and absorber oil in the manufacture of polyolefin articles authorized for food contact use.	In an amount not to exceed that required to produce intended effect, consistent with good manufacturing practice.
As a lubricant of fibers of textiles authorized for food contact use.	At a use level not to exceed 0.15 percent by weight of finished fibers.
As a component of adhesives	Complying with § 175.105 of this chapter.
As a defoamer in the manufacture of paper and paperboard	Complying with § 176.210 of this chapter.
As a defoamer in coatings	Complying with § 176.200 of this chapter.

§ 178.3690 Pentaerythritol adipate-stearate.

Pentaerythritol adipate-stearate identified in paragraph (a) of this section may be safely used as a lubricant in the fabrication of rigid and semirigid polyvinyl chloride and/or vinyl chloride-propylene copolymers complying with § 177.1980 of this chapter used as articles or components of articles that contact food, excluding food with alcohol content greater than 8 percent under conditions of use of E, F, and G described in Table 2 in § 175.300(d) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, pentaerythritol adipate-stearate is an ester of pentaerythritol with stearic and adipic acids, having 71 percent stearic acid and 14 percent adipic acid.

(b) *Specifications.* Pentaerythritol adipate-stearate has the following specifications:

(1) Melting point (dropping) of 49°-52° C as determined by ASTM method D566-76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(2) Acid value not to exceed 15 as determined by ASTM method D1386-78, "Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Saponification number of 270-280 as determined by ASTM method D1387-78, "Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) Iodine number not to exceed 2 as determined by Iodine Absorption Number, Hanus Method, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," sections 28.018-28.019, 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) The total amount of ester (calculated as free pentaerythritol) shall not exceed 0.4 percent by weight of the polyvinyl chloride and/or the vinyl chloride-propylene copolymers complying with § 177.1980.

[45 FR 1018, Jan. 4, 1980, as amended at 47 FR 11848, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984]

§ 178.3700 Petrolatum.

Petrolatum may be safety used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petrolatum complies with the specifications set forth in the United States Pharmacopeia XX (1980) for white petrolatum in the National Formulary XV (1980) for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter:

Ultraviolet absorbance per centimeter pathlength:

Millimicrons	Maximum
280 to 289	0.25
290 to 299	.20
300 to 359	.14
360 to 400	.04

(c) It is used or intended for use as a protective coating of the surfaces of metal or wood tanks used in fermentation process, in an amount not in excess of that required to produce its intended effect.

(d) Petrolatum as defined by this section may be used for the functions described and within the limitations prescribed by specific regulations in Parts 175, 176, 177, and 178 of this chapter which prescribe uses of petrolatum. For the purpose of cross-reference, such specific regulations include: §§ 175.105, 175, 176, 177, and 178 of this chapter 177.2600, and 177.2800 of this chapter and § 178.3570.

(e) Petrolatum may contain any antioxidant permitted in food by regulations issued pursuant to section 409 of the act, in an amount not greater than that required to produce its intended effect.

[42 FR 14609, Mar. 15, 1977, as amended at 49 FR 10113, Mar. 19, 1984]

§ 178.3710 Petroleum wax.

Petroleum wax may be safely used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed in this section.

(b) The petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter.

Ultraviolet absorbance per centimeter pathlength:

Millimicrons	Maximum
280 to 289	0.15
290 to 299	.12
300 to 359	.08
360 to 400	.02

(c) Petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(d) Petroleum wax may contain a total of not more than 1 weight percent of residues of the following polymers when such residues result from use of the polymers as processing aids (filter aids) in the production of the petroleum wax: Homopolymers and/or copolymers derived from one or more of the mixed *n*-alkyl (C_{12}, C_{14}, C_{16}, and C_{18}) methacrylate esters where the C_{12} and C_{14} alkyl groups are derived from coconut oil and the C_{16} and C_{18} groups are derived from tallow.

(e) Petroleum wax may contain 2-hydroxy-4-*n*-octoxybenzophenone as a stabilizer at a level not to exceed 0.01 weight percent of the petroleum wax.

(f) Petroleum wax may contain poly(alkylacrylate) (CAS Reg. No. 27029-57-8), as described in § 172.886(c)(2) of this chapter, as a processing aid in the manufacture of petroleum wax.

[42 FR 14609, Mar. 15, 1977, as amended at 51 FR 19545, May 30, 1986]

§ 178.3720 Petroleum wax, synthetic.

Synthetic petroleum wax may be safely used in applications and under the same conditions where naturally derived petroleum wax is permitted in Subchapter B of this chapter as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definition and specifications prescribed in § 172.888 of this chapter.

§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed in compliance with §§ 561.310 and 561.340 of this chapter, or that are intended for use in contact with dried food in compliance with §§ 193.60 and 193.390 of this chapter.

§ 178.3740 Plasticizers in polymeric substances.

Subject to the provisions of this regulation, the substances listed in paragraph (b) of this section may be safely used as plasticizers in polymeric substances used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

Substances	Limitations
Butylbenzyl phthalate	For use only: 1. As provided in §§ 175.105 and 176.180 of this chapter. 2. In polymeric substances used in food-contact articles complying with § 175.300, § 175.320, or § 176.170 of this chapter: *Provided*, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate. 3. In polymeric substances used in other permitted food-contact articles: *Provided*, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate; and *Provided further*, That the finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 mg. per square inch, as determined by the methods prescribed in § 175.300(e) of this chapter.

Substances	Limitations
1,3-Butylene glycoladipic acid polyester (1,700–2,200 molecular weight) terminated with a 16 percent by weight mixture of myristic, palmitic, and stearic acids.	For use at levels not exceeding 33 percent by weight of polyvinyl chloride homopolymers used in contact with food (except foods that contain more than 8 percent of alcohol) at temperatures not to exceed room temperature. The average thickness of such homopolymers in the form in which they contact food shall not exceed 0.004 inch.
Di(C_7, C_9-alkyl) adipate, in which the C_7, C_9-alkyl groups are derived from linear alpha olefins by the oxo process.	For use only under the conditions listed below, and excluding use as a component of resinous and polymeric coatings described in § 175.300 of this chapter. 1. At levels not to exceed 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not to exceed 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymer in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
Di-*n*-alkyl adipate made from C_6, C_8-C_{10} (predominately C_8 and C_{10}) or C_6-C_{10} synthetic fatty alcohols complying with § 172.864 of this chapter.	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in which they contact food shall not exceed 0.002 inch.
Dicyclohexyl phthalate	For use only: 1. As provided in §§ 175.105, 176.170, 176.180, and 177.1200 of this chapter. 2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.
Di(2-ethylhexyl) adipate	
Diisononyl adipate	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.

Substances	Limitations
	3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
Diisononyl phthalate	For use only at levels not exceeding 43 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, and VIII, at temperatures not exceeding room temperature. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
Di(2-ethylhexyl) azelate	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty, nonalcoholic food having a fat and oil content not exceeding a total of 30 percent by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Di-*n*-hexylazelate	For use only: 1. In polymeric substances used in contact with nonfatty food. 2. In polymeric substances used in contact with fatty food and limited to use at levels not exceeding 15 pct by weight of such polymeric substance except as provided under limitation 3. 3. At levels greater than 15 but not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F or G described in Table 2 of § 176.170(c) of this chapter, with fatty food having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Dihexyl phthalate	For use only: 1. As provided in § 175.105 of this chapter. 2. In articles that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI-B, and VIII.
Diphenyl phthalate	For use only: 1. As provided in § 175.105 of this chapter. 2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.
Epoxidized butyl esters of linseed oil fatty acids	Iodine number, maximum 5; oxirane oxygen, minimum 7.8 pct.
Epoxidized linseed oil	Iodine number, maximum 5; oxirane oxygen, minimum 9-pct.
Mineral oil, white	
Polybutene, hydrogenated (minimum viscosity at 99° F, 39 Saybolt Universal seconds, as determined by ASTM methods D445-82 ("Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity)") and D2161-82 ("Standard Method for Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity"), and bromine number of 3 or less, as determined by ASTM method D1492-78 ("Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration"), which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408	For use only: 1. In polymeric substances used in contact with non-fatty food. 2. In polyethylene complying with § 177.1520 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking. 3. In polystyrene complying with § 177.1640 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 5 pct by weight of the polystyrene, and further provided that such plasticized polystyrene shall not be used as a component of articles intended for packing or holding food during cooking.

Substances	Limitations
Polyisobutylene (mol weight 300-5,000)	For use in polyethylene complying with § 177.1520 of this chapter, provided that the polyisobutylene is added in an amount not exceeding 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking
Polyisobutylene complying with § 177.1420 of this chapter	
Polypropylene glycol (CAS registry No. 25322-69-4) (minimum mean molecular weight 1,200)	For use only in polystyrene plastics, identified in § 177.1640(a)(1), in an amount not to exceed 6 pct by weight of the finished food-contact article
Propylene glycol azelate (average mol weight 3,000)	For use only at levels not exceeding 41 pct by weight of permitted polyvinyl chloride coatings. Such coatings shall be used only as bulk food contact surfaces of articles intended for repeated use, complying with § 177.2600 of this chapter
Triethylene glycol	Diethylene glycol content not to exceed 0.1 pct.
2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	For use only in cellulosic plastics in an amount not to exceed 15 pct by weight of the finished food-contact article, provided that the finished plastic article contacts food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, VI-B, VII-B, and VIII.

(c) The use of the plasticizers in any polymeric substance or article subject to any regulation in Parts 174, 175, 176, 177, 178 and 179 of this chapter must comply with any specification and limitations prescribed by such regulation for the finished form of the substance or article.

[42 FR 14609, Mar. 15, 1977, as amended at 42 FR 44223, Sept. 2, 1977; 45 FR 56052, Aug. 22, 1980; 48 FR 5748, Feb. 15, 1984; 49 FR 10113, Mar. 19, 1984; 51 FR 47011, Dec. 30, 1986]

§ 178.3750 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used as a component of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(b) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is 350 or higher and no more than 0.5 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is below 350, when tested by the analytical methods prescribed in § 172.820(b) of this chapter.

(c) The provisions of paragraph (b) of this section are not applicable to polyethylene glycols used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 178.3760 Polyethylene glycol (400) monolaurate.

Polyethylene glycol (400) monolaurate containing not more than 0.1 percent by weight of ethylene and/or diethylene glycol may be used at a level not to exceed 0.3 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with § 177.1500 of this chapter.

§ 178.3770 Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids.

Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids identified in this section may be safely used as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The polyhydric alcohol diesters identified in this paragraph may be used as lubricants in the fabrication of vinyl chloride plastic food-contact articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 177.1980 of this chapter. Such diesters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthoffen process) montan wax acids by either ethylene glycol or 1,3-butanediol with or without neutralization of unreacted carboxylic groups with calcium hydroxide:

(1) Dropping point 76°-105° C, as determined by ASTM method D566-76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(2) Acid value 10-20, as determined by ASTM method D1386-78 ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100, L St. NW., Washington, DC 20408) using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.

(3) Saponification value 100-160, as determined by ASTM method D1387-78 ("Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits as follows, as determined by the analytical method described in this subparagraph:

Ultraviolet absorbance per centimeter pathlength.

Millimicrons	Maximum
280 to 289	0.07
290 to 299	.06
300 to 359	.04
360 to 400	.01

ANALYTICAL METHOD

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 1,000-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable balljoint at the top.

Chromatographic tube. 1,200 millimeters in length, inside diameter to be 16.5 millimeters ±0.5 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 1,255 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately 3/16-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jackets. Conical, for 500-milliliter and 1,000-milliliter separatory funnels. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flasks (optional). A 250-milliliter or 500-milliliter capacity and a 1-liter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide) 2-

liter distillation flask with heating mantle; Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Oil bath. Capable of heating to 90 °C.

Spectrophotometric cells. Fused quartz cells, optical pathlength in the range 1.000 centimeter ± 0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons-400 millimicrons with spectral slit width of 0.2 millimicron or less; under instrument operating conditions for these absorbance measurements. The spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ± 0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ± 0.05 at 0.4 absorbance.

Wavelength repeatability, ± 0.2 millimicron.

Wavelength accuracy, ± 1.0 millimicron.

Recording time, 50 seconds.

Time constant, 0.6 second.

Sensitivity, 30.

Ordinate scale, 90-100 percent transmission through scale.

Abscissa scale, 8X.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane and benzene designated in the list following this paragraph shall pass the following test:

To be specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make up to 25 milliliters volume. Determine the absorbance in the 1-centimeter pathlength cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter pathlength between 280 mμ and 400 mμ.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference point between 280 mμ-400 mμ. The absorbance per centimeter pathlength shall not exceed 0.00 in this range. If necessary, purify by filtering through a column containing 100 grams of aluminum oxide (use same grade as described below) in the lower half and 100 grams of activated silica gel in the upper half keeping the column at 150 °C., for a period of 15 hours or overnight. The first 100 milliliters of eluate are used. Purification can also be accomplished by distillation.

Dimethyl sulfoxide. Pure grade, clear, water-white, m.p. 18 minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500-milliliter separatory funnel, mix and allow to cool for 5-10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40-milliliter extractives three times with 50-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate* under "Reagents and materials" for preparation of filter), into a 250-milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40-milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash the second and first separatory funnels successively with a 10-milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25-milliliter volume. Determine the absorbance in 1-centimeter pathlength cells compared to isooctane as reference. The absorbance of the solution should not exceed 0.02 per centimeter pathlength in the 280 mμ-400 mμ range. (NOTE: Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.)

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[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2-liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50 grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrafluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the filtrate to a 2-liter separatory funnel and draw off the dimethyl sulfoxide into the 2-liter distillation flask of the vacuum distillation assembly and distill at approximately 3-millimeter Hg pressure or less. Discard the first 200-milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until approximately 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stoppered bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Aluminum oxide (80-200 mesh Woelm neutral activity grade 1 [Brockmann], Alupharm Chemicals, New Orleans, La., or equivalent). Pipette 1 milliliter of distilled water into a dry 250-milliliter Erlenmeyer flask equipped with a ground-glass stopper. Stopper the flask and rotate it in such a manner as to completely wet out the inside surfaces. When this has been done add 180 grams of the aluminum oxide and shake until no lumps or wet spots remain. Allow to stand at room temperature for a period of 2 hours. At the end of this time the water should be evenly distributed throughout the aluminum oxide powder, and it should have the same free flowing properties as the original material (flow velocity with water 0.2 milliliter per minute). At this point the aluminum oxide has an activity of 1 as expressed in Brockmann degrees, and the amount of added water is 0.5 percent by volume. This product is used in toto and as is, without further screening.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter pathlength between 280 mμ and 400 mμ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

PROCEDURE

Before proceeding with analysis of a sample, determine the absorbance in a 1-centimeter path cell between 250 mμ and 400 mμ for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectrum after the complete procedure as prescribed. The absorbance per centimeter pathlength following the complete procedure should not exceed 0.04 in the wavelength range from 280 mμ to 299 mμ, inclusive, nor 0.02 in the wavelength range from 300 mμ to 400 mμ. If in either spectrum the characteristic benzene peaks in the 250 mμ-260 mμ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again. Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

In a 1-liter separatory funnel place a representative 25-gram sample of wax, add 50 milliliters of isooctane, heat gently, stir until the wax is in solution; add 100 milliliters of preequilibrated sulfoxide-phosphoric acid mixture and shake, making sure it remains in solution. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate* under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane using an aspirator vacuum under nitrogen and in an oil bath temperature of approximately 90° C. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Reserve the residue for column chromatography on the aluminum oxide. Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 180 grams of the aluminum oxide and pour the adsorbent mixture into the chromatographic tube in approximately 30-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 180 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 80 centimeters in depth. Turn off the vacuum and remove the suction flask. Dissolve the hexadecane residue in 10 milliliters of warm benzene and decant the solution onto the column and allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 10-milliliter portions of benzene swirling the flask repeatedly each time to assure adequate washing of the residue. Fix the 1,000-milliliter reservoir onto the top of the chromatographic column. Just before the final 10-milliliter wash reaches the top of the adsorbent, add 670 milliliters of benzene to the reservoir and continue the percolation at the 2-3 milliliter per minute rate until a total of 670 milliliters of benzene has been utilized. Collect the eluate in a clean 1-liter Erlenmeyer flask (or optionally into a 1-liter evaporation flask). Allow the column to drain until most of the solvent mixture is removed. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic Solvents." Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 250 mμ-400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ-260 mμ region, evaporate the solution to remove benzene by the procedure under "Organic Solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in paragraph (a) of this section, the wax meets the ultraviolet absorbance specifications.

(b) The polyhydric alcohol diesters identified in this paragraph may be used as release agents in resinous and polymeric coatings for polyolefin films complying with § 175.320 of this chapter. Such diesters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthoffen process) montan wax acids with equimolar proportions of ethylene glycol and 1,3-butanediol:

(1) Dropping point 77°-82° C, as determined by ASTM method D566-76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubricating Grease," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(2) Acid value 25-35, as determined by ASTM method D1386-78 ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 1:2 ratio.

(3) Saponification value 135-150, as determined by ASTM method D1387-78 ("Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits specified in paragraph (a)(4) of this section, as determined by the analytical method described therein.

(c) The polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, identified in paragraph (a) or (b) of this section, may also be used as a component of an aqueous dispersion of vinylidene chloride copolymers, subject to the conditions described in paragraphs (c) (1) and (2) of this section.

(1) The aqueous dispersion of the additive contains not more that 18 percent polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, not more than 2 percent poly(oxyethylene) (minimum 20 moles of ethylene oxide) oleyl ether (CAS Reg. No. 9005-98-2), and not more than 1 percent poly(oxyethylene) (minimum 3 moles ethylene oxide) cetyl alcohols (CAS Reg. No. 9004-95-9).

(2) The aqueous dispersion described in paragraph (c)(1) of this section is used as an additive to aqueous dispersions of vinylidene chloride copolymers, regulated in §§ 175.300, 175.320, 175.360, 176.170, 176,180, and 177.1630 of this chapter, at levels not to exceed 1.5 percent (solids basis) in the finished coating.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11848, Mar. 19, 1982; 49 FR 10113, Mar. 19, 1984; 51 FR 33895, Sept. 24, 1986]

§ 178.3780 Polyhydric alcohol esters of long chain monobasic acids.

Polyhydric alcohol esters of long chain monobasic acids identified in this section may be safely used as lubricants in the fabrication of polyvinyl chloride and/or polyvinyl chloride copolymer articles complying with

§ 177.1980 of this chapter that contact food of Types I, II, IV-B, VI-B, VII-B, and VIII identified in Table 1 in § 176.170(c) of this chapter under conditions of use E, F, and G described in Table 2 in § 176.170(c) of this chapter, subject to the provisions of this section.

(a) *Identity*. For the purpose of this section, polyhydric alcohol esters of long chain monobasic acids consist of polyhydric alcohol esters having number average molecular weights in the range of 1,050 to 1,700. The esters are produced by the reaction of either ethylene glycol or glycerol with long chain monobasic acids containing from 9 to 49 carbon atoms obtained by the ozonization of long chain *alpha*-olefins, the unreacted carboxylic acids in the formation of the glycerol esters being neutralized with calcium hydroxide to produce a composition having up to 2 percent by weight calcium. The *alpha*-olefins, obtained from the polymerization of ethylene, have 20 to 50 carbon atoms and contain a minimum of 75 percent by weight straight chain *alpha*-olefins and not more than 25 percent vinylidene compounds.

(b) *Specifications*. The polyhydric alcohol esters have the following specifications:

(1) Melting point of 60-80° C for the ethylene glycol ester and 90-105° C for the glycerol ester as determined by the Fisher Johns method as described in "Semimicro Qualitative Organic Analysis—The Systematic Identification of Organic Compounds," by Cheronis and Entrikin, 2d Ed., Interscience Publishers, NY, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Acid value 15-25 for each ester as determined by the A.O.C.S. method Tria-64T "Titer Test," which is incorporated by reference. Copies are available from American Association of Oil Chemists, 36 East Wacker Drive, Chicago, IL 60601, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The method is modified to use as the acid solvent a 1:1 volume mixture of anhydrous isopropyl alcohol and toluene. The solution is titrated with 0.1*N* methanolic sodium hydroxide.

(3) Saponification value 120-160 for the ethylene glycol ester and 90-130 for the glycerol ester as determined the A.O.C.S. method Tria-64T "Saponification Value," which is incorporated by reference. Copies are available from American Association of Oil Chemists, 36 East Wacker Drive, Chicago, IL 60601, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) Ultraviolet absorbance as specified in § 178.3770(a)(4) of this chapter when tested by the analytical method described therein.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11849, Mar. 19, 1982]

§ 178.3790 Polymer modifiers in semirigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admixed, alone or in mixture with other permitted polymers, as modifiers in semirigid and rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers and/or from vinyl chloride copolymers complying with § 177.1950, § 177.1970, and/or § 177.1980 of this chapter, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polymer modifiers are identified as follows:

(1) Acrylic polymers identified in this subparagraph provided that such polymers contain at least 50 weight-percent of polymer units derived from one or more of the monomers listed in paragraph (a)(1)(i) of this section.

(i) Homopolymers and copolymers of the following monomers:

n-Butyl acrylate.
n-Butyl methacrylate.
Ethyl acrylate.
Methyl methacrylate.

(ii) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1)(i) of this section with one or more of the following monomers:

Acrylonitrile.
Butadiene.
α-Methylstyrene.
Styrene.
Vinylidene chloride.

(iii) Polymers identified in paragraphs (a)(1) (i) and (ii) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

Acrylic acid.
1,3-Butylene glycol dimethacrylate.
Divinylbenzene.
Methacrylic acid.

(iv) Mixtures of polymers identified in paragraph (a)(1) (i), (ii), and (iii) of this section; provided that no chemical reactions, other than addition reactions, occur when they are mixed.

(2) Polymers identified in paragraph (a)(1) of this section combined during their polymerization with butadiene-styrene copolymers; provided that no chemical reactions, other than addition reactions, occur when they are combined. Such combined polymers may contain 50 weight-percent or more of total polymer units derived from the butadiene-styrene copolymers.

(b) The polymer content of the finished plastic food-contact article consists of:

(1) Not less than 80 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section and not more than 5 weight-percent of polymer units derived from polymers identified in paragraph (a)(1) of this section and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers; or

(2) Not less than 50 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section, not more than 50 weight-percent of polymer units derived from homopolymers and/or copolymers of ethyl acrylate and methyl methacrylate, and not more than 30 weight-percent of polymer units derived from copolymers of methyl methacrylate, α-methylstyrene and acrylonitrile and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers.

(c) No chemical reactions, other than addition reactions, occur among the vinyl chloride polymers and the modifying polymers present in the polymer mixture used in the manufacture of the finished plastic food-contact article.

(d) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields extractives not to exceed the limits prescribed in § 177.1010 (b) (1), (2), (3), and (4) of this chapter when tested by the methods prescribed in § 177.1010 (c) of this chapter.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 178.3800 Preservatives for wood.

Preservatives may be safely used on wooden articles that are used or intended for use in packaging, transporting, or holding raw agricultural products subject to the provisions of this section:

(a) The preservatives are prepared from substances identified in paragraph (b) of this section and applied in amounts not to exceed those necessary to accomplish the technical effect of protecting the wood from decay, mildew, and water absorption.

(b) The substances permitted are as follows:

List of substances	Limitations
Copper-8-quinolinolate	
Mineral spirits	
Paraffin wax	Used singly or in combination so as to constitute not less than 50% of the solids.

List of substances	Limitations
Petroleum hydrocarbon resin, produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene type from distillates of cracked petroleum stocks	Do
Pentachlorophenol and its sodium salt	Not to exceed 50 p.p.m. in the treated wood, calculated as pentachlorophenol
Rosins and rosin derivatives	As provided in § 178 3870
Zinc salt of sulfonated petroleum	

§ 178.3850 Reinforced wax.

Reinforced wax may be safely used as an article or component of articles intended for use in producing, manufacturing, packing, processing, transporting, or holding food subject to the provisions of this section.

(a) Reinforced wax consists of petroleum wax to which have been added certain optional substances required in its production, or added to impart desired physical or technical properties.

(b) The quantity of any optional adjuvant substance employed in the production of or added to reinforced wax does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation provided in this section.

(c) Any substance employed in the production of reinforced wax, including any optional substance, that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, conforms with any specification in such regulation.

(d) The substances and optional adjuvant substances employed in the production of or added to reinforced wax include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction for use in reinforced wax and used in accordance with such sanction or approval.

(3) Substances identified in this subparagraph and subject to any limitations provided therein:

List of substances	Limitations
Copolymer of isobutylene modified with isoprene	
Petroleum wax, Type I and Type II	
Polyethylene	
Rosins and rosin derivatives as provided in § 178 3870	
Synthetic wax polymer as described in § 176 170(a)(5) of this chapter	Not to exceed 5 percent by weight of the petroleum wax

(e) Reinforced wax conforming with the specifications in this paragraph is used as provided in paragraph (e)(2) of this section.

(1) The chloroform-soluble portion of the water extract obtained by exposing reinforced wax to demineralized water at 70° F for 48 hours shall not exceed 0.5 milligram per square inch of food-contact surface.

(2) It is used as a packaging material or component of packaging materials for cheese and cheese products.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 1288, Jan. 12, 1982]

§ 178.3860 Release agents.

Substances listed in paragraph (b) of this section may be safely used as release agents in petroleum wax complying with § 178.3710 and in polymeric resins that contact food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect or any limitations prescribed in this section.

(b) Release agents:

List of substances	Limitations
Erucamide (erucylamide)	
N,N-Dioleoylethylenediamine	For use only in polyvinyl chloride films in amounts such that the concentration of the substance in these films in the form in which the films contact food shall not exceed 0.055 milligram of the substance per square inch of film

List of substances	Limitations
Oleyl palmitamide	
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b).	For use only subject to the limitations prescribed for hydrogenated polybutene under § 178.3740(b).
Poly(vinyl acetate/vinyl *N*-octadecylcarbamate) (CAS Reg. No. 70892-21-6) produced by the reaction between stoichiometrically equivalent amounts of octadecyl isocyanate and vinyl alcohol/vinyl acetate copolymer; minimum average molecular weight is 500,000.	For use only in application to the backing of pressuresensitive adhesive tapes at levels not to exceed 0.2 milligram per square centimeter (1.29 milligrams per square inch) of backing.
Rice bran wax	For use only in plastics intended for contact with dry foods identified as Type VIII in Table 1 of § 176.170(c) of this chapter, at levels not in excess of 1.0 percent by weight of the polymer.
Saturated fatty acid amides manufactured from fatty acids derived from animal, marine, or vegetable fats and oils.	
Stearyl erucamide	

[42 FR 14609, Mar. 15, 1977, as amended at 44 FR 69649, Dec. 4, 1979; 46 FR 51902, Oct. 23, 1981]

§ 178.3870 Rosins and rosin derivatives.

The rosins and rosin derivatives identified in paragraph (a) of this section may safely be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rosins and rosin derivatives are identified as follows:

(1) Rosins:

(i) Gum rosin, refined to color grade of K or paler.

(ii) Wood rosin, refined to color grade of K or paler.

(iii) Tall oil rosin, refined to color grade of K or paler.

(iv) Dark tall oil rosin, a fraction resulting from the refining of tall oil rosin produced by multicolumnar distillation of crude tall oil to effect removal of fatty acids and pitch components and having a saponification number of from 110-135 and 32 percent-44 percent rosin acids.

(v) Dark wood rosin, all or part of the residue after the volatile terpene oils are distilled from the oleoresin extracted from pine wood.

(2) Modified rosins manufactured from rosins identified in paragraph (a)(1) of this section:

(i) Partially hydrogenated rosin, catalytically hydrogenated to a maximum refractive index of 1.5012 at 100° C, and a color of WG or paler.

(ii) Fully hydrogenated rosin, catalytically hydrogenated to a maximum dehydroabietic acid content of 2 percent, a minimum drop-softening point of 79° C, and a color of X or paler.

(iii) Partially dimerized rosin, dimerized by sulfuric acid catalyst to a drop-softening point of 95°-105° C and a color of WG or paler.

(iv) Fully dimerized rosin, dimerized by sulfuric acid catalyst, and from which sufficient nondimerized rosin has been removed by distillation to achieve a minimum drop-softening point of 143° C, and a color of H or paler.

(v) Disproportionated rosin, catalytically disproportionated to a minimum dehydroabietic acid content of 35 percent, a maximum abietic acid content of 1 percent, a maximum content of substituted phenanthrenes (as retene) of 0.25 percent, and a color of WG or paler.

(3) Rosin esters manufactured from rosins and modified rosins identified in paragraphs (a)(1) and (2) of this section:

(i) Glycerol ester of wood rosin purified by steam stripping to have an acid number of 3 to 9, a drop-softening point of 88°-96° C, and a color of N or paler.

(ii) Glycerol ester of partially hydrogenated wood rosin, having an acid number of 3 to 10, a drop-softening point of 79°-88° C, and a color of N or paler.

(iii) Glycerol ester of partially dimerized rosin, having an acid number of 3 to 8, a drop-softening point of 109°-119° C, and a color of M or paler.

(iv) Glycerol ester of fully dimerized rosin, having an acid number of 5 to 16, a drop-softening point of 165°-175° C, and a color of H or paler.

(v) Glycerol ester of maleic anhydride-modified wood rosin, having an acid number of 30 to 40, a drop-softening point of 138°-146° C, a color of M or paler, and a saponification number less than 280.

(vi) Methyl ester of rosin, partially hydrogenated, purified by steam stripping to have an acid number of 4 to 8, a refractive index of 1.5170 to 1.5205 at 20° C, and a viscosity of 23 to 66 poises at 25° C.

(vii) Pentaerythritol ester of wood rosin, having an acid number of 6 to 16, a drop-softening point of 109°-116° C, and a color of M or paler.

(viii) Pentaerythritol ester of partially hydrogenated wood rosin, having an acid number of 7 to 18, a drop-softening point of 102°-110° C, and a color of K or paler.

(ix) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 8 to 16, a drop-softening point of 154°-162° C, a color of M or paler, and having a saponification number less than 280.

(x) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 9 to 16, a drop-softening point of 130°-140° C, a color of N or paler, and having a saponification number less than 280.

(xi) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 134 to 145, a drop-softening point of 127°-137° C, a color of M or paler, and having a saponification number less than 280.

(xii) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 30 to 40, a drop-softening point of 131°-137° C, a color of N or paler, and having a saponification number less than 280.

(xiii) Pentaerythritol ester of maleic anhydride-modified wood rosin, further modified by reaction with 4,4′-isopropyl-idenediphenol-formaldehyde condensate, having an acid number of 10 to 22, a drop-softening point of 162°-172° C, a color of K or paler, a saponification number less than 280, and a maximum ultraviolet absorbance of 0.14 at 296 mμ (using a 1-centimeter cell and 200 milligrams of the rosin ester per liter of solvent consisting of ethyl alcohol made alkaline by addition of 0.1 percent of potassium hydroxide).

(xiv) Mixed methyl and pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 73 to 83, a drop-softening point of 113°-123° C, a color of M or paler, and a saponification number less than 280.

(xv) Triethylene glycol ester of partially hydrogenated wood rosin, having an acid number of 2 to 10, a color of K or paler, and a viscosity of 350 to 425 seconds Saybolt at 100° C.

(xvi) Glycerol ester of maleic anhydride-modified wood rosin, having an acid number of 17 to 23, a drop-softening point of 136°-140° C, a color of M or paler, and a saponification number less than 280. For use only in cellophane complying with § 177.1200 of this chapter.

(xvii) Citric acid-modified glycerol ester of rosin, having an acid number less than 20, a drop-softening point of 105°-115° C, and a color of K or paler. For use only as a blending agent in coatings for cellophane complying with § 177.1200 of this chapter.

(xviii) Glycerol ester of tall oil rosin, purified by steam stripping to have an acid number of 5-12, a softening point of 80°-88° C, and a color of N or paler.

(xix) Glycerol ester of maleic anhydride-modified tall oil rosin, having an acid number of 30 to 40, a drop-softening point of 141°-146° C, a color of N or paler, and a saponification number less than 280.

(xx) Glycerol ester of disproportionated tall oil rosin, having an acid number of 5 to 10, a drop-softening point of 84°-93° C, a color of WG or paler, and a saponification number less than 180.

(4) Rosin salts and sizes—Ammonium, calcium, potassium, sodium, or zinc salts of rosin manufactured by the partial or complete saponification of any one of the rosins or modified rosins identified in paragraph (a)(1) and (2) of this section, or blends there-

of, and with or without modification by reaction with one or more of the following:

(i) Formaldehyde.

(ii) Fumaric acid.

(iii) Maleic anhydride.

(iv) Saligenin.

(b) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(c) The use in any substance or article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter shall conform with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(d) The provisions of this section are not applicable to rosins and rosin derivatives identified in § 175.300(b)(3)(v) of this chapter and used in resinous and polymeric coatings complying with § 175.300 of this chapter.

(e) The provisions of this section are not applicable to rosins and rosin derivatives identified in § 175.105(c)(5) of this chapter and used in defoaming agents complying with § 176.210 of this chapter, food-packaging adhesives complying with § 175.105 of this chapter, and rubber articles complying with § 177.2600 of this chapter.

(f) The analytical methods for determining whether rosins and rosin derivatives conform to the specifications prescribed in paragraph (a) of this section are as follows:

(1) Color: Color shall be as determined by ASTM method D509-70 (Reapproved 1981), "Standard Methods of Sampling and Grading Rosin," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(2) Refractive index: Refractive index shall be as determined by ASTM method D1747-62 (Reapproved 1978), "Standard Test Method for Refractive Index of Viscous Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(3) Acid number: Acid number shall be as determined by ASTM method D465-82, "Standard Test Methods for Acid Number of Rosin," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(4) Viscosity: Viscosity in poises shall be as determined by ASTM method D1824-66 (Reapproved 1980), "Standard Test Method for Apparent Viscosity of Plastisols and Organosols at Low Shear Rates by Brookfield Viscometer," and in Saybolt seconds by ASTM method D88-81, "Standard Test Method for Saybolt Viscosity," which are incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(5) Softening point: Softening point shall be as determined by ASTM method E28-67, "Standard Test Method for Softening Point by Ring and Ball Apparatus" (Reapproved 1977), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(6) Analytical methods for determining drop-softening point, saponification number, and any other specifications not listed under paragraphs (f)(1) through (5) of this section, titled: (i) "Determination of Abeitic Acid and Dehydroabietic Acid in Rosins"; (ii) "Determination of Softening Point of Solid Resins"; (iii) "Determination of Saponification Number of Rosin Esters," and (iv) "Determination of Phenolic Modification of Rosin Derivatives," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11849, Mar. 19, 1982; 49 FR 10113, Mar. 19, 1984]

§ 178.3900 Sodium pentachlorophenate.

Sodium pentachlorophenate may be safely used as a preservative for ammonium alginate employed as a processing aid in the manufacture of polyvinyl chloride emulsion polymers intended for use as articles or components of articles that contact food at temperatures not to exceed room temperature. The quantity of sodium pentachlorophenate used shall not exceed 0.5 percent by weight of ammonium alginate solids.

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

The substances listed in this section may be safely used in surface lubricants employed in the manufacture of metallic articles that contact food, subject to the provisions of this section.

(a) The following substances may be used in surface lubricants used in the rolling of metallic foil or sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of metallic food-contact surface:

(1) Substances identified in paragraphs (b)(1) and (2) of this section.

(2) Substances identified in this paragraph.

List of substances	Limitations
Acetate esters derived from synthetic straight chain alcohols (complying with § 172.864 of this chapter) that have even numbers of carbon atoms in the range C_8-C_{18}	
alpha-Alkyl-*omega*-hydroxypoly-(oxyethylene) produced by the condensation of 1 mole of C_{10}-C_{16} straight chain primary alcohols with an average of 3 moles of ethylene oxide (CAS Reg. No. 68002-97-1)	
Benzotriazole (CAS Reg. No. 95-14-7)	
Tert-Butyl alcohol	
Di(2-ethylhexyl)phthalate	
Diethyl phthalate	
Dimers, trimers, and/or their partial methyl esters; such dimers and trimers are of unsaturated C_{18} fatty acids derived from animal and vegetable fats and oils and/or tall oil, and such partial methyl esters meet the following specifications: Saponification value 180-200, acid value 70-130, and maximum iodine value 120	For use only at a level not to exceed 10 percent by weight of finished lubricant formulation.
Di-*n*-octyl sebacate	
Ethylenediaminetetraacetic acid, sodium salts	
Isopropyl alcohol	
Isopropyl oleate	
Methyl esters of coconut oil fatty acids	
Methyl esters of fatty acids (C_{16}-C_{18}) derived from animal and vegetable fats and oils	
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b)	
Polyethylene glycol (400) monostearate	
Polyisobutylene (minimum molecular weight 300)	
Polyoxyethylated (5 moles) tallow amine (CAS Reg. No. 61791-26-2)	
Polyvinyl alcohol	
Sodium nitrite	For use only as a rust inhibitor in lubricant formulations provided the total residual sodium nitrite on the metallic article in the form in which it contacts food does not exceed 0.007 milligram per square inch of metallic food-contact surface.

List of substances	Limitations
Sodium petroleum sulfonate, MW 440–450 (CAS Reg. No. 68608-24-4) derived from naphthenic oil having a Saybolt viscosity range of 500–600 Saybolt Universal Seconds (SUS at 37–8 °C (100 °F) as determined by ASTM method D88-81, "Standard Test Method for Saybolt Viscosity," which is incorporated by reference. Copies are available from the American Society for Testing Materials, 1961 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	
Synthetic alcohol mixture of straight-and branched-chain alcohols that have even numbers of carbon atoms in the range C_6-C_{18} and that are prepared from ethylene, aluminum, and hydrogen such that the finished synthetic alcohol mixture contains not less than 75 pct of straight-chain primary alcohols and contains not less than 85 pct total C_{10} and C_{12} alcohols.	
Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 pct normal alcohols; not less than 96.5 pct C_{12}–C_{15} alcohols; and not more than 2.5 pct alpha, omega C_{13}–C_{16} diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications: Molecular weight, 207 ± 4; hydroxyl number, 266–276.	For use at a level not to exceed 8 pct by weight of the finished lubricant formulation.
Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 percent normal alcohols; not less than 93 pct C_{12}-C_{13} alcohols, not more than 5 pct C_{11}–C_{15} alcohols, and not more than 2.5 pct alpha, omega, C_{13}-C_{14} diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications: Molecular weight 194 ± 5; hydroxyl number, 283–296	For use only at a level not to exceed 8 pct by weight of the finished lubricant formulation.
Tallow, sulfonated	
Triethanolamine	

(3) Mineral oil conforming to the identity prescribed in § 178.3620(c).

(4) Light petroleum hydrocarbons identified in paragraph (a)(4) (i) of this section: *Provided*, That the total residual lubricant on the metallic article in the form in which it contacts food meets the ultraviolet absorbance limits prescribed in paragraph (a) (4) (ii) of this section as determined by the analytical method described in paragraph (a) (4) (iii) of this section.

(i) Light petroleum hydrocarbons are derived by distillation from virgin petroleum stocks or are synthesized from petroleum gases. They are chiefly paraffinic, isoparaffinic, napthenic, or aromatic in nature, and meet the following specifications:

(*a*) Initial boiling point is 24 °C minimum and final boiling point is 288 °C maximum, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(*b*) Nonvolatile residue is 0.005 gram per 100 milliliters, maximum, as determined by ASTM method D381-80, "Standard Test Method for Existent Gum in Fuels by Jet Evaporation," when the final boiling point is 121 °C or above and by ASTM method D1353-78, "Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products," when the final boiling point is below 121 °C. These ASTM methods are incorporated by reference. The availability of these incorporations by reference is given in paragraph (a)(4)(i)(*a*) of this section.

(*c*) Saybolt color 20 minimum as determined by ASTM method D156-82, "Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(i)(*a*) of this section.

(*d*) Aromatic component content shall not exceed 32 percent.

(*e*) Conforms with ultraviolet absorbance limits prescribed in § 178.3620(c) as determined by the analytical method described therein.

(ii) Ultraviolet absorbance limits on residual lubricants are as follows:

Wavelength (mμ)	Maximum absorbance per 5 centimeters optical pathlength
280-289	0.7
290-299	.6
300-359	.4
360-400	.09

(iii) The analytical method for determining ultraviolet absorbance limits on residual lubricants is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent, residues, etc. Examine all glassware including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard-taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Special range 250 millicrons-400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Soxhlet apparatus. 60-millimeter diameter body tubes fitted with condenser and 500-milliliter round-bottom boiling flask. A supply of paper thimbles to fit is required.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane (2,2,4-trimethylpentane) shall pass the following test:

Place 180 milliliters of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains.

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[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The accuracy is to be determined by comparison with the standard values at 210, 345, and 400 millimicrons.

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

n-Hexadecane, 99-percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 mμ-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corp., Camas, Washington, or equivalent). Absorbance (1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength	Absorbance (maximum)
261.5	1.00
270	.20
275	.09
280	.06
300	.015

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-milliliter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 mμ and 400 mμ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without a metal sample. The absorbance per centimeter path length should not exceed 0.02 in the wavelength range from 280 mμ to 400 mμ.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

PROCEDURE

Sample. Select metal foil or sheet stock for the test which has not been previously contaminated by careless handling or exposure to atmospheric dust and fumes. A commercial coil in the form supplied for spindle mounting in a packaging line or wrapping machine is most suitable. Strip off the outside turn of metal and discard. Carefully avoid contamination or damage from handling the metal (wear gloves). Remove a 16-18-foot length from the coil and place it on a flat surface protected by a length of new kraft paper. Cut four 15-foot strips from the sample, each 3 inches wide (avoid tearing the edges of the strips). Using a piece of suitable glass rod, roll the strips of metal into loose coils and insert each into a Soxhlet thimble. Each turn of coil should be visibly separated from the adjacent turn.

Extraction. Fill each of the four Soxhlet tubes with purified isooctane (see under heading "Reagents and Materials," above) until siphon action occurs and then refill the tube body. Supply heat to the boiling flask and allow extraction to continue for at least 8 hours or until repeated weighings of the dried and cooled coil show no further weight loss.

Combine the isooctane extracts from the four Soxhlet units in a suitable beaker, rinsing each tube and flask into the beaker with fresh purified solvent. Evaporate the solvent under an atmosphere of inert gas (nitrogen) to residual volume of 50-60 milliliters and transfer this solution to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of pre-equilibrated isooctane to give a total volume of the residue and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portion of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliter of isooctane. Draw off and discard the aqueous layer. Wash each of the 80 milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate pre-washed with isooctane (see sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in 5-centimeter pathlength cells compared to isooctane as reference between 280mμ-400mμ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a metal sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the residue meets the ultraviolet absorbance specifications.

(b) The following substances may be used in surface lubricants used to facilitate the drawing, sampling, or forming of metallic articles from rolled foil or sheet stock by further processing provided that the total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.2 milligram per square inch of food-contact surface:

(1) Antioxidants used in compliance with regulations in Parts 170 through 189 of this chapter.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetyl tributyl citrate	
Acetyl triethyl citrate	
Butyl stearate	
Castor oil	
Dibutyl sebacate	
Di(2-ethylhexyl) azelate	
Di(2-ethylhexyl) sebacate	
Diisodecyl phthalate	
Dimethylpolysiloxane	Conforming to the identity prescribed in § 181.28 of this chapter
Dipropylene glycol	
Epoxidized soybean oil	Conforming to the identity prescribed in § 181.27 of this chapter
Fatty acids derived from animal and vegetable fats and oils, and salts of such acids, single or mixed, as follows: Aluminum Magnesium Potassium Sodium Zinc	
Fatty alcohols, straight-chain with even number carbon atoms (C_{10} or greater)	
Isobutyl stearate	

List of substances	Limitations
Lanolin	
Linoleic acid amide	
Mineral oil	Conforming to the identity prescribed in § 178.3620 (a) or (b)
Mono-, di-, and tristearyl citrate	
Oleic acid amide	
Palmitic acid amide	
Petrolatum	Conforming to the identity prescribed in § 178.3700
Polyethylene glycol (molecular weight 300 or greater)	Mono- and diethylene glycol content not to exceed a total of 0.2 pct.
Stannous stearate	
Stearic acid amide	
Stearyl stearate	
Tetrakis[methylene (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane (CAS Registry No. 6683-19-8)	For use at a level not to exceed 0.5 percent by weight of the finished surface lubricant formulation
Triethylene glycol	Diethylene glycol content not to exceed 0.1 pct.
Wax, petroleum	Complying with § 178.3710

(c) The substances identified in paragraph (a)(2) of this section may be used in surface lubricants used to facilitate the drawing, stamping, and forming of metallic articles from rolled foil and sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of food-contact surface.

(d) Subject to any prescribed limitations, the quantity of surface lubricant used in the manufacture of metallic articles shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any technical effect in the food itself.

(e) The use of the surface lubricants in the manufacture of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications prescribed by such regulation for the finished form of the article.

(f) Any substance that is listed in this section and the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter shall comply with any applicable specifications prescribed by such regulation.

[42 FR 14609, Mar. 15, 1977, as amended at 48 FR 238, Jan. 4, 1983; 49 FR 10113, Mar. 19, 1984; 49 FR 29579, July 23, 1984; 50 FR 36874, Sept. 10, 1985; 52 FR 10223, Mar. 31, 1987]

§ 178.3930 Terpene resins.

The terpene resins identified in paragraph (a) of this section may be safely used as components of polypropylene film intended for use in contact with food, and the terpene resins identified in paragraph (b) of this section may be safely used as components of polyolefin film intended for use in contact with food;

(a) Terpene resins consisting of the hydrogenated polymers of terpene hydrocarbons obtainable from sulfate turpentine and meeting the following specifications: Drop-softening point of 118°-138° C; iodine value less than 20.

(b) Terpene resins consisting of polymers of beta-pinene and meeting the following specifications: Acid value less than 1; saponification number less than 1; color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.

§ 178.3940 Tetraethylene glycol di-(2-ethylhexoate).

Tetraethylene glycol di-(2-ethylhexoate) containing not more than 22 parts per million ethylene and/or diethylene glycols may be used at a level not to exceed 0.7 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with § 177.1500 of this chapter.

§ 178.3950 Tetrahydrofuran.

Tetrahydrofuran may be safely used in the fabrication of articles intended for packaging, transporting, or storing foods, subject to the provisions of this section.

(a) It is used as a solvent in the casting of film from a solution of polymeric resins of vinyl chloride, vinyl acetate, or vinylidene chloride that have been polymerized singly or copolymerized with one another in any combination, or it may be used as a solvent in the casting of film prepared from vinyl chloride copolymers complying with § 177.1980 of this chapter.

(b) The residual amount of tetrahydrofuran in the film does not exceed 1.5 percent by weight of film.

§ 178.3970 Ultramarine blue.

Ultramarine blue may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) It is used as a colorant in the manufacture of the following articles:

(1) Flexible, semirigid, and rigid plastic materials.

(2) Textiles and textile fibers as provided in § 177.2800 of this chapter.

(b) The quantity used shall not exceed the amount reasonably required to accomplish the intended effect.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

Subpart A—[Reserved]

Subpart B—Radiation and Radiation Sources

Sec.
179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.
179.25 General provisions for food irradiation.
179.26 Ionizing radiation for the treatment of food.
179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.
179.39 Ultraviolet radiation for the processing and treatment of food.

Subpart C—Packaging Materials for Irradiated Foods

Sec.
179.45 Packaging materials for use during the irradiation of prepackaged foods.

AUTHORITY: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 703, 704, 52 Stat. 1046-1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 373, 374); 21 CFR 5.10, 5.11.

SOURCE: 42 FR 14635, Mar. 15, 1977, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Radiation and Radiation Sources

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

Sources of radiation for the purposes of inspection of foods, for inspection of packaged food, and for controlling food processing may be safely used under the following conditions:

(a) The radiation source is one of the following:

(1) X-ray tubes producing X-radiation from operation of the tube source at energy levels of 300 kilovolt peak or lower.

(2) Sealed units producing radiations at energy levels of not more than 2.2 million electron volts from one of the following isotopes: Americium-241, cesium-137, cobalt-60, iodine-125, krypton-85, radium-226, and strontium-90.

(3) Sealed units producing neutron radiation from the isotope Californium-252 (CAS Reg. No. 13981-17-4) to measure moisture in food.

(b) To assure safe use of these radiation sources:

(1) The label of the sources shall bear, in addition to the other information required by the Act:

(i) Appropriate and accurate information identifying the source of radiation.

(ii) The maximum energy of radiation emitted by X-ray tube sources.

(2) The label or accompanying labeling shall bear:

(i) Adequate directions for installation and use.

(ii) A statement that no food shall be exposed to radiation sources listed in paragraph (a) (1) and (2) of this section so as to receive an absorbed dose in excess of 1,000 rads.

(iii) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(3) of this section so as to receive an absorbed doese in excess of 200 millirads.

[42 FR 14635, Mar. 15, 1977, as amended at 48 FR 46022, Oct. 11, 1983]

§ 179.25 General provisions for food irradiation.

For the purposes of § 179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of Part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods shall comply with § 179.45.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with a scheduled process established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

(e) A food irradiation processor shall maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treated, lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(Approved by the Office of Management and Budget under control number 0910-0186)

[51 FR 13399, Apr. 18, 1986]

§ 179.26 Ionizing radiation for the treatment of food.

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.

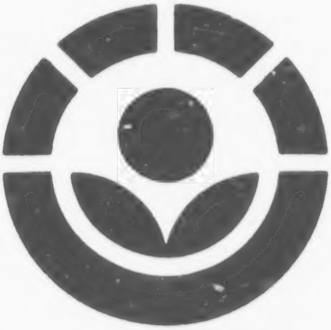
(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts.

(b) *Limitations.*

Use	Limitations
For control of *Trichinella spiralis* in pork carcasses or fresh non-heat-processed cuts of pork carcasses	Minimum dose 0.3 kGy (30 krad). Maximum dose not to exceed 1 kGy (100 krad)
For growth and maturation inhibition of fresh foods	Not to exceed 1 kGy (100 krad)
For disinfestation of arthropod pests in food	Do
For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes)	Not to exceed 10 kGy (1 Mrad)
For microbial disinfection of the following dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, vegetable seasonings, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives	Not to exceed 30 kGy (3 Mrad)

Use	Limitations
The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends	

(c) *Labeling.* (1) The label and labeling of retail packages of foods irradiated in conformance with paragraph (b) of this section shall bear the following logo



along with either the statement "Treated with radiation" or the statement "Treated by irradiation" in addition to information required by other regulations. The logo shall be placed prominently and conspicuously in conjunction with the required statement.

(2) For irradiated foods not in package form, the required logo and phrase "Treated with radiation" or "Treated by irradiation" shall be displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. As an alternative, each item of food may be individually labeled. In either case, the information must be prominently and conspicuously displayed to purchasers. The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated.

(3) For a food, any portion of which is irradiated in conformance with paragraph (b) of this section, the label and labeling and invoices or bills of lading shall bear either the statement "Treated with radiation—do not irradiate again" or the statement "Treated by irradiation—do not irradiate again" when shipped to a food manufacturer or processor for further processing, labeling, or packing.

(4) The wording requirements of paragraphs (c)(1) and (2) of this section pertaining to the label and labeling of retail packages of food shall expire April 18, 1988, unless extended by the Food and Drug Administration by publication for notice and comment in the FEDERAL REGISTER.

[51 FR 13399, Apr. 18, 1986]

§ 179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.

Radiofrequency radiation, including microwave frequencies, may be safely used for heating food under the following conditions:

(a) The radiation source consists of electronic equipment producing radio waves with specific frequencies for this purpose authorized by the Federal Communications Commission.

(b) The radiation is used or intended for use in the production of heat in food wherever heat is necessary and effective in the treatment or processing of food.

§ 179.39 Ultraviolet radiation for the processing and treatment of food.

Ultraviolet radiation for the processing and treatment of food may be safely used under the following conditions:

(a) The radiation sources consist of ultraviolet emission tubes designed to emit wavelengths within the range of 2200-3000 Angstrom units with 90 percent of the emission being the wavelength 2537 Angstrom units.

(b) The ultraviolet radiation is used or intended for use as follows:

Irradiated food	Limitations	Use
Food and food products	Irradiated with 2,200 to 3,000 A emissions, without ozone production; high fat-content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 2,537 A radiation) per 5 to 10 ft^2	Surface microorganism control.
Potable water	Irradiated with 2,200 to 3,000 A emissions, without ozone production; coefficient of absorption, 0.19 per cm or less; flow rate, 100 gal/h per watt of 2,537 A radiation; water depth, 1 cm or less; lamp-operating temperature, 36 to 46 C.	Sterilization of water used in food production.

Subpart C—Packaging Materials for Irradiated Foods

§ 179.45 Packaging materials for use during the irradiation of prepackaged foods.

The packaging materials identified in this section may be safely subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods, subject to the provisions of this section and to the requirement that no induced radioactivity is detectable in the packaging material itself:

(a) The radiation of the food itself shall comply with regulations in this part.

(b) The following packaging materials may be subjected to a dose of radiation, not to exceed 1 megarad, unless otherwise indicated, incidental to the use of gamma radiation in the radiation treatment of prepackaged foods:

(1) Nitrocellulose-coated or vinylidene chloride copolymer-coated cellophane complying with § 177.1200 of this chapter.

(2) Glassine paper complying with § 176.170 of this chapter.

(3) Wax-coated paperboard complying with § 176.170 of this chapter.

(4) Polyolefin film prepared from one or more of the basic olefin polymers complying with § 177.1520 of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (c)(2)(i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(5) Kraft paper prepared from unbleached sulfate pulp to which rosin, complying with § 178.3870 of this chapter, and alum may be added. The kraft paper is used only as a container for flour and is irradiated with a dose not exceeding 50,000 rads.

(6) Polyethylene terephthalate film prepared from the basic polymer as described in § 177.1630(d)(4)(i) of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (c)(2)(i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(iii) Coatings consisting of polyethylene conforming to § 177.1520 of this chapter.

(7) Polystyrene film prepared from styrene basic polymer. The finished film may contain adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter.

(8) Rubber hydrochloride film prepared from rubber hydrochloride basic polymer having a chlorine content of 30-32 weight percent and having a maximum extractable fraction of 2 weight percent when extracted with *n*-hexane at reflux temperature for 2 hours. The finished film may contain adjuvant substances used in compli-

ance with §§ 178.3740 and 181.22 through 181.30 of this chapter.

(9) Vinylidene chloride-vinyl chloride copolymer film prepared from vinylidene chloride-vinyl chloride basic copolymers containing not less than 70 weight percent of vinylidene chloride and having a viscosity of 0.50–1.50 centipoises as determined by ASTM method D729-81, "Standard Specification for Vinylidene Chloride Molding Compounds," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408. The finished film may contain adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter.

(10) Nylon 11 conforming to § 177.1500 of this chapter.

(c) The following packaging materials may be subjected to a dose of radiation, not to exceed 6 megarads incidental to the use of gamma or X-radiation in the radiation processing of prepackaged foods:

(1) Vegetable parchments, consisting of a cellulose material made from waterleaf paper (unsized) treated with concentrated sulfuric acid, neutralized, and thoroughly washed with distilled water.

(2) Films prepared from basic polymers and with or without adjuvants, as follows:

(i) Polyethylene film prepared from the basic polymer as described in § 177.1520(a) of this chapter. The finished film may contain one or more of the following added substances:

Substances	Limitations
Amides of erucic, linoleic, oleic, palmitic, and stearic acid	Not to exceed 1 pct by weight of the polymer
BHA as described in § 172.110 of this chapter	Do.
BHT as described in § 172.115 of this chapter	Do.
Calcium and sodium propionates	Do.
Petroleum wax as described in § 178.3710 of this chapter	Do.
Polypropylene, noncrystalline, as described in § 177.1520(c) of this chapter	Not to exceed 2 pct by weight of the polymer
Stearates of aluminum, calcium, magnesium, potassium, and sodium as described in § 172.863(a) of this chapter.	Not to exceed 1 pct by weight of the polymer
Triethylene glycol as described in § 178.3740(b) of this chapter	Do.
Mineral oil as described in § 178.3620 (a) or (b) of this chapter	Do.

(ii) Polyethylene terephthalate film prepared from the basic polymer as described in § 177.1630(e)(4)(ii) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (c)(2)(i) of this section.

(iii) Nylon 6 films prepared from the nylon 6 basic polymer as described in § 177.1500(a)(6) of this chapter and meeting the specifications of item 6.1 of the table in § 177.1500(b) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (c)(2)(i) of this section.

(iv) Vinyl chloride-vinyl acetate copolymer film prepared from the basic copolymer containing 88.5 to 90.0 weight percent of vinyl chloride with 10.0 to 11.5 weight percent of vinyl acetate and having a maximum volatility of not over 3.0 percent (1 hour at 105° C) and viscosity not less than 0.30 determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," Method A, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(9) of this section. The finished film may contain one or more of the added substances listed in paragraph (c)(2)(i) of this section.

(d) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14635, Mar. 15, 1977, as amended at 49 FR 10113, Mar. 19, 1984]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

Subpart A—General Provisions

Sec.
180.1 General.

Subpart B—Specific Requirements for Certain Food Additives

180.22 Acrylonitrile copolymers.
180.25 Mannitol.
180.30 Brominated vegetable oil.
180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 180.1 General.

(a) Substances having a history of use in food for human consumption or in food contact surfaces may at any time have their safety or functionality brought into question by new information that in itself is not conclusive. An interim food additive regulation for the use of any such substance may be promulgated in this subpart when new information raises a substantial question about the safety or functionality of the substance but there is a reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved by further study.

(b) No interim food additive regulation may be promulgated if the new information is conclusive with respect to the question raised or if there is a reasonable likelihood that the substance is harmful or that continued use of the substance will result in harm to the public health.

(c) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 10 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

(1) Use of the substance in food or food contact surfaces must comply with whatever limitations the Commissioner deems to be appropriate under the circumstances.

(2) Within 60 days following the effective date of the regulation, an interested person shall satisfy the Commissioner in writing that studies adequate and appropriate to resolve the questions raised about the substance have been undertaken, or the Food and Drug Administration may undertake the studies. The Commissioner may extend this 60-day period if necessary to review and act on proposed protocols. If no such commitment is made, or adequate and appropriate studies are not undertaken, an order shall immediately be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(3) A progress report shall be filed on the studies every January 1 and July 1 until completion. If the progress report is inadequate or if the Commissioner concludes that the studies are not being pursued promptly and diligently or if interim results indicate a reasonable likelihood that a health hazard exists, an order will promptly be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(4) If nonclinical laboratory studies are involved, studies filed with the Commissioner shall include, with respect to each study, either a statement that the study has been or will be conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(5) [Reserved]

(6) If clinical investigations involving human subjects are involved, such investigations filed with the Commissioner shall include, with respect to each investigation, a statement that

the investigation either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it has been or will be conducted in compliance with the requirements for informed consent set forth in Part 50 of this chapter.

(d) Promptly upon completion of the studies undertaken on the substance, the Commissioner will review all available data, will terminate the interim food additive regulation, and will either issue a food additive regulation or will require elimination of the substance from the food supply.

(e) The Commissioner may consult with advisory committees, professional organizations, or other experts in the field, in evaluating:

(1) Whether an interim food additive regulation is justified,

(2) The type of studies necessary and appropriate to resolve questions raised about a substance,

(3) Whether interim results indicate the reasonable likelihood that a health hazard exists, or

(4) Whether the data available at the conclusion of those studies justify a food additive regulation.

(f) Where appropriate, an emergency action level may be issued for a substance subject to paragraph (a) of this section that is not an approved food additive, pending the issuance of a final interim food additive regulation. Such an action level shall be issued pursuant to sections 306 and 402(a) of the act to identify, based upon available data, a safe level of use for the substance. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed interim food additive regulation. Where the available data do not permit establishing an action level for the safe use of a substance, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

(Secs. 409, 501, 502, 503, 505, 506, 507, 512-516, 520, 701, 706, 52 Stat. 1049-1053 as amended, 1055, 1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 82 Stat. 343-351, 90 Stat. 540-560 (21 U.S.C. 348, 351, 352, 353, 355, 356, 357, 360b-360f, 371, 376); secs. 215, 301, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 241, 262, 263b-236n))

[42 FR 14636, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 42 FR 52821, Sept. 30, 1977; 46 FR 8952, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 50 FR 7492, Feb. 22, 1985]

Subpart B—Specific Requirements for Certain Food Additives

§ 180.22 Acrylonitrile copolymers.

Acrylonitrile copolymers may be safely used on an interim basis as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by a method of analysis titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408, are as follows:

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food contact surface—0.003 milligram/square inch when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch

when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(b) Where necessary, current regulations permitting the use of acrylonitrile copolymers shall be revised to specify limitations on acrylonitrile/mercaptan complexes utilized in the production of acrylonitrile copolymers. Such copolymers, if they contain reversible acrylonitrile/mercaptan complexes and are used in other than repeated-use conditions, shall be tested to determine the identity of the complex and the level of the complex present in the food-contact article. Such testing shall include determination of the rate of decomposition of the complex at temperatures of 100° F, 160° F, and 212° F using 3 percent acetic acid as the hydrolic agent. Acrylonitrile monomer levels, acrylonitrile/mercaptan complex levels, acrylonitrile oligomer levels, descriptions of the analytical methods used to determine the complex and the acrylonitrile migration, and validation studies of these analytical methods shall be submitted by June 9, 1977, to the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives, 200 C St. SW., Washington, D.C. 20204, unless an extension is granted by the Food and Drug Administration for good cause shown. Analytical methods for the determination of acrylonitrile complexes with *n*-dodecyl-mercaptan, n-octyl mercaptan, and 2-mercaptoethanol, titled "Determination of β-Dodecyl-mercaptopropionitrile in NR-16R Aqueous Extracts" and "Measurement of β-(2-Hdroxyethylmercapto) Propionitrile in Heptane Food-Simulating Solvent," are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The following data shall be provided for finished food-contact articles intended for repeated use:

(1) Qualitative and quantitative migration values at a time equivalent to initial batch usage, utilizing solvents and temperatures appropriate to the intended conditions of use.

(2) Qualitative and quantitative migration values at the time of equilibrium extractions, utilizing solvents and temperatures appropriate to the intended conditions of use.

(3) Data on the volume and/or weight of food handled during the initial batch time period(s), during the equilibrium test period, and over the estimated life of the food-contact surface.

(d) Where acrylonitrile copolymers represent only a minor component of a polymer system, calculations based on 100 percent migration of the acrylonitrile component may be submitted in lieu of the requirements of paragraphs (a), (b), and (c) of this section in support of the continued safe use of acrylonitrile copolymers.

(e) On or before September 13, 1976, any interested person shall satisfy the Commissioner of Food and Drugs that toxicological feeding studies adequate and appropriate to establish safe conditions for the use of acrylonitrile copolymers have been, or soon will be, undertaken. Toxicity studies of acrylonitrile monomer shall include: (1) Lifetime feeding studies with a mammalian species, preferably with animals exposed in utero to the chemical, (2) studies of multigeneration reproduction with oral administration of the test material, (3) assessment of teratogenic and mutagenic potentials, (4) subchronic oral administration in a nonrodent mammal, (5) tests to determine any synergistic toxic effects between acrylonitrile monomer and cyanide ion, and (6) a literature search on the effects of chronic ingestion of hydrogen cyanide. Data on levels of acrylamide extractable from acrylonitrile copolymers shall also be submitted. Protocols of testing should be submitted for review to the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF-330), 200 C St. SW., Washington, D.C. 20204.

(f) Acrylonitrile copolymers may be used in contact with food only if authorized in Parts 174 through 179 or § 181.32 of this chapter, except that other uses of acrylonitrile copolymers in use prior to June 14, 1976, may continue under the following conditions:

(1) On or before August 13, 1976, each use of acrylonitrile copolymers in a manner not authorized by § 181.32 of this chapter or Parts 174 through 179 of this chapter shall be the subject of a notice to the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF-330), 200 C St. SW., Washington, DC 20204. Such notice shall be accompanied by a statement of the basis, including any articles and correspondence, on which the user in good faith believed the use to be prior-sanctioned. The Commissioner of Food and Drugs shall, by notice in the FEDERAL REGISTER, identify any use of acrylonitrile copolymers not in accordance with this paragraph. Those uses are thereafter unapproved food additives and consequently unlawful.

(2) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall be the subject of a petition submitted on or before December 13, 1976, in accordance with § 171.1 of this chapter, unless an extension of time is granted by the Food and Drug Administration for good cause shown. Any application for extension shall be by petition submitted in accordance with the requirements of Part 2 of this chapter. If a petition is denied, in whole or in part, those uses subject to the denial are thereafter unapproved food additives and consequently unlawful.

(3) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall meet the acrylonitrile monomer extraction limitation set forth in paragraph (a) of this section and shall be subject to the requirements of paragraph (b) of this section.

(g) In addition to the requirements of this section, the use of acrylonitrile copolymers shall comply with all applicable requirements in other regulations in this part.

[42 FR 14636, Mar. 15, 1977, as amended at 47 FR 11850, Mar. 19, 1982]

§ 180.25 Mannitol.

(a) Mannitol is the chemical 1,2,3,4,5, 6,-hexanehexol ($C_6H_{14}O_6$) a hexahydric alcohol, differing from sorbitol principally by having a different optical rotation. Mannitol is produced by the electrolytic reduction, or the transition metal catalytic hydrogenation, of sugar solutions containing glucose or fructose.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 188-190, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in § 170.3(o)(1) of this chapter, formulation aid as defined in § 170.3(o) (14) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, nutritive sweetener as defined in § 170.3(o)(21) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, surface-finishing agent as defined in § 170.3(o)(30) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed 98 percent in pressed mints and 5 percent in all other hard candy and cough drops as defined in § 170.3(n)(25) of this chapter, 31 percent in chewing gum as defined in § 170.3(n)(6) of this chapter, 40 percent in soft candy as defined in § 170.3(n)(38) of this chapter, 8 percent in confections and frostings as defined in § 170.3(n)(9) of this chapter, 15 percent in nonstandardized jams and jellies, commercial, as defined in § 170.3(n)(28) of this chapter, and at levels less than 2.5 percent in all other foods.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 20 grams of mannitol shall bear the statement "Excess consumption may have a laxative effect".

(f) In accordance with § 180.1, adequate and appropriate feeding studies have been undertaken for this substance. Continued uses of this ingredient are contingent upon timely and adequate progress reports of such tests, and no indication of increased risk to public health during the test period.

(g) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 180.30 Brominated vegetable oil.

The food additive brominated vegetable oil may be safely used in accordance with the following prescribed conditions:

(a) The additive complies with specifications prescribed in the "Food Chemicals Codex," 3d Ed. (1981), pp. 40-41, which is incorporated by reference, except that free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20418.

(b) The additive is used on an interim basis as a stabilizer for flavoring oils used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 parts per million in the finished beverage, pending the outcome of additional toxicological studies on which periodic reports at 6-month intervals are to be furnished and final results submitted to the Food and Drug Administration promptly after completion of the studies.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

The food additives saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin may be safely used as sweetening agents in food in accordance with the following conditions, if the substitution for nutritive sweeteners is for a valid special dietary purpose and is in accord with current special dietary food regulations and policies or if the use or intended use is for an authorized technological purpose other than calorie reduction:

(a) Saccharin is the chemical, 1,2-benzisothiazolin-3-one - 1,1 - dioxide ($C_7H_5NO_3S$). The named salts of saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt.

(b) The food additives meet the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22, 62, 266-267, 297-299, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) Authority for such use shall expire when the Commissioner receives the final reports on the ongoing studies in Canada and publishes an order on the safety of saccharin and its salts based on those reports and other available data.

(d) The additives are used or intended for use as a sweetening agent only in special dietary foods, as follows:

(1) In beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, in amounts not to exceed 12 milligrams of the additive, calculated as saccharin, per fluid ounce.

(2) As a sugar substitute for cooking or table use, in amounts not to exceed 20 milligrams of the additive, calculated as saccharin, for each expressed teaspoonful of sugar sweetening equivalency.

(3) In processed foods, in amounts not to exceed 30 milligrams of the additive, calculated as saccharin, per serving of designated size.

(e) The additives are used or intended for use only for the following technological purposes:

(1) To reduce bulk and enhance flavors in chewable vitamin tablets, chewable mineral tablets, or combinations thereof.

(2) To retain flavor and physical properties of chewing gum.

(3) To enhance flavor of flavor chips used in nonstandardized bakery products.

(f) To assure safe use of the additives, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate mixes of the additive for manufacturing purposes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive, expressed as saccharin, in any intermediate mix.

(iii) Adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraphs (d) and (e) of this section.

(2) The label of any finished food product containing the additive shall bear:

(i) The name of the additive.

(ii) The amount of the additive, calculated as saccharin, as follows:

(*a*) For beverages, in milligrams per fluid ounce;

(*b*) For cooking or table use products, in milligrams per dispensing unit;

(*c*) For processed foods, in terms of the weight or size of a serving which shall be that quantity of the food containing 30 milligrams or less of the additive.

(iii) When the additive is used for calorie reduction, such other labeling as is required by Part 105 or § 100.130 of this chapter.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

Subpart A—General Provisions

Sec.
181.1 General.
181.5 Prior sanctions.

Subpart B—Specific Prior-Sanctioned Food Ingredients

Sec.
181.22 Certain substances employed in the manufacture of food-packaging materials.
181.23 Antimycotics.
181.24 Antioxidants.
181.25 Driers.
181.26 Drying oils as components of finished resins.
181.27 Plasticizers.
181.28 Release agents.
181.29 Stabilizers.
181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.
181.32 Acrylonitrile polymers and resins.
181.33 Sodium nitrate and potassium nitrate.
181.34 Sodium nitrite and potassium nitrite.

AUTHORITY: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055—1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10.

SOURCE: 42 FR 14638, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 181.1 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the Act is exempt from classification as a food additive. The Commissioner will publish in this part all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the Act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the Act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of a final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the Act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055 and 72 Stat. 1784-1788, as amended (21 U.S.C. 321(s), 348, 371(a)))

[42 FR 14638, Mar. 15, 1977, as amended at 42 FR 52821, Sept. 30, 1977]

§ 181.5 Prior sanctions.

(a) A prior sanction shall exist only for a specific use(s) of a substance in food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958.

(b) The existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the Act but not from the other adulteration or the misbranding provisions of the Act.

(c) All known prior sanctions shall be the subject of a regulation published in this part. Any such regulation is subject to amendment to impose whatever limitation(s) or condition(s) may be necessary for the safe use of the ingredient, or revocation to prohibit use of the ingredient, in order to prevent the adulteration of food in violation of section 402 of the Act.

(d) In proposing, after a general evaluation of use of an ingredient, regulations affirming the GRAS status of substances added directly to human food in Part 184 of this chapter or substances in food-contact surfaces in Part 186 of this chapter, or establishing a food additive regulation for substances added directly to human food in Parts 172 and 173 of this chapter or food additives in food-contact surfaces in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, the Commissioner shall, if he is aware of any prior sanction for use of the ingredient under conditions different from those proposed in the regulation, concurrently propose a separate regulation covering such use of the ingredient under this part. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any food additive or GRAS regulation promulgated after a general evaluation of use of an ingredient constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to a proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this part, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

Subpart B—Specific Prior-Sanctioned Food Ingredients

§ 181.22 Certain substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the substances listed in §§ 181.23, 181.24, 181.25, 181.26, 181.27, 181.28, 181.29, and 181.30 in the manufacture of packaging materials. So used, these substances are not considered "food additives" within the meaning of section 201(s) of the Act, provided that they are of good commercial grade, are suitable for association with food, and are used in accordance with good manufacturing practice. For the purpose of this subpart, good manufacturing practice for food-packaging materials includes the restriction that the quantity of any of these substances which becomes a component of food as a result of use in food-packaging materials shall not be intended to accomplish any physical or technical effect in the food itself, shall be reduced to the least amount reasonably possible, and shall not exceed any limit specified in this subpart.

[42 FR 56728, Oct. 28, 1977]

§ 181.23 Antimycotics.

Substances classified as antimycotics, when migrating from food-packaging material shall include:

Calcium propionate.
Methylparaben (methyl p-hydroxybenzoate).
Propylparaben (propyl *p*-hydroxybenzoate).
Sodium benzoate.
Sodium propionate.
Sorbic acid.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.24 Antioxidants.

Substances classified as antioxidants, when migrating from food-packaging material (limit of addition to food, 0.005 percent) shall include:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Dilauryl thiodipropionate.
Distearyl thiodipropionate.
Gum guaiac.
Nordihydroguairetic acid.
Propyl gallate.
Thiodipropionic acid.
2,4,5-Trihydroxy butyrophenone.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.25 Driers.

Substances classified as driers, when migrating from food-packaging material shall include:

Cobalt caprylate.
Cobalt linoleate.
Cobalt naphthenate.
Cobalt tallate.
Iron caprylate.
Iron linoleate.
Iron naphthenate.
Iron tallate.
Manganese caprylate.
Manganese linoleate.
Manganese naphthenate.
Manganese tallate.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.26 Drying oils as components of finished resins.

Substances classified as drying oils, when migrating from food-packaging material (as components of finished resins) shall include:

Chinawood oil (tung oil).
Dehydrated castor oil.
Linseed oil.
Tall oil.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.27 Plasticizers.

Substances classified as plasticizers, when migrating from food-packaging material shall include:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
p-tert-Butylphenyl salicylate.
Butyl stearate.
Butylphthalyl butyl glycolate.
Dibutyl sebacate.
Di-(2-ethylhexyl) phthalate (for foods of high water content only).
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate (for foods of high water content only).
Diphenyl-2-ethylhexyl phosphate.
Epoxidized soybean oil (iodine number maximum 6; and oxirane oxygen, minimum, 6.0 percent).
Ethylphthalyl ethyl glycolate.
Glycerol monooleate.
Monoisopropyl citrate.
Mono, di-, and tristearyl citrate.
Triacetin (glycerol triacetate).
Triethyl citrate.
3-(2-Xenolyl)-1,2-epoxypropane.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 50 FR 49536, Dec. 3, 1985]

§ 181.28 Release agents.

Substances classified as release agents, when migrating from food-packaging material shall include:

Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups, no more than 18 percent loss in weight after heating 4 hours at 200° C.; viscosity 300 centisokes, 600 centisokes at 25° C. specific gravity 0.96 to 0.97 at 25° C, refractive index 1.400 to 1.404 at 25° C).
Linoleamide (linoleic acid amide).
Oleamide (oleic acid amide).
Palmitamide (palmitic acid amide).

Stearamide (stearic acid amide).

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.29 Stabilizers.

Substances classified as stabilizers, when migrating from food-packaging material shall include:

Aluminum mono-, di-, and tristearate.
Ammonium citrate.
Ammonium potassium hydrogen phosphate.
Calcium glycerophosphate.
Calcium phosphate.
Calcium hydrogen phosphate.
Calcium oleate.
Calcium acetate.
Calcium carbonate.
Calcium ricinoleate.
Calcium stearate.
Disodium hydrogen phosphate.
Magnesium glycerophosphate.
Magnesium stearate.
Magnesium phosphate.
Magnesium hydrogen phosphate.
Mono-, di-, and trisodium citrate.
Mono-, di-, and tripotassium citrate.
Potassium oleate.
Potassium stearate.
Sodium pyrophosphate.
Sodium stearate.
Sodium tetrapyrophosphate.
Stannous stearate (not to exceed 50 parts per million tin as a migrant in finished food).
Zinc orthophosphate (not to exceed 50 parts per million zinc as a migrant in finished food).
Zinc resinate (not to exceed 50 parts per million zinc as a migrant in finished food).

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.

Substances used in the manufacture of paper and paperboard products used in food packaging shall include:

Aliphatic polyoxyethylene ethers.*
1-Alkyl (C_6-C_{18})3-amino-3-aminopropane monoacetate.*
Borax or boric acid for use in adhesives, sizes, and coatings.*
Butadiene-styrene copolymer.
Chromium complex of perfluoro-octane sulfonyl glycine for use on paper and paperboard which is waxed.*
Disodium cyanodithioimidocarbamate with ethylene diamine and potassium *N*-methyl dithiocarbamate and/or sodium 2-mercaptobenzothiazole (slimicides).*
Ethyl acrylate and methyl methacrylate copolymers of itaconic acid or methacrylic acid for use only on paper and paperboard which is waxed.*
Hexamethylene tetramine as a setting agent for protein, including casein.*
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2-alkyl (C_6-C_{17}) imidazolinium chloride.*
Itaconic acid (polymerized).
Melamine formaldehyde polymer.
Methyl acrylate (polymerized).
Methyl ethers or mono-, di-, and tripropylene glycol.*
Myristo chromic chloride complex.
Nitrocellulose.
Polyethylene glycol 400.
Polyvinyl acetate.
Potassium pentachlorophenate as a slime control agent.*
Potassium trichlorophenate as a slime control agent.*
Resins from high and low viscosity polyvinyl alcohol for fatty foods only.
Rubber hydrochloride.
Sodium pentachlorophenate as a slime control agent.*
Sodium-trichlorophenate as a slime control agent.*
Stearato-chromic chloride complex.
Titanium dioxide.*
Urea formaldehyde polymer.
Vinylidine chlorides (polymerized).

§ 181.32 Acrylonitrile copolymers and resins.

(a) Acrylonitrile copolymers and resins listed in this section, containing less than 30 percent acrylonitrile and complying with the requirements of paragraph (b) of this section, may be safely used as follows:

(1) *Films.* (i) Acrylonitrile/butadiene/styrene copolymers—no restrictions.

(ii) Acrylonitrile/butadiene copolymers—no restrictions.

(iii) Acrylonitrile/butadiene copolymer blended with vinyl chloride-vinyl acetate (optional at level up to 5 percent by weight of the vinyl chloride resin) resin—for use only in contact with oleomargarine.

(iv) Acrylonitrile/styrene copolymer—no restrictions.

(2) *Coatings.* (i) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resins—for use only on

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*Under the conditions of normal use, these substances would not reasonably be expected to migrate to food, based on available scientific information and data.

paper and paperboard in contact with meats and lard.

(ii) Polyvinyl chloride resin blended with either acrylonitrile/butadiene copolymer or acrylonitrile/butadiene styrene copolymer mixed with neoprene, for use as components of conveyor belts to be used with fresh fruits, vegetables, and fish.

(iii) Acrylonitrile/butadiene/styrene copolymer—no restrictions.

(iv) Acrylonitrile/styrene copolymer—no restrictions.

(3) *Rigid and semirigid containers.* (i) Acrylonitrile/butadiene/styrene copolymer—for use only as piping for handling food products and for repeated-use articles intended to contact food.

(ii) Acrylonitrile/styrene resin—no restrictions.

(iii) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resin—for use only as extruded pipe.

(b) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by using the method of analysis titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food-Simulating Solvents," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408, are as follows:

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food-contact surface—0.003 milligram/square inch when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food-contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(c) Acrylonitrile monomer may present a hazard to health when ingested. Accordingly, any food-contact article containing acrylonitrile copolymers or resins that yield acrylonitrile monomer in excess of that amount provided for in paragraph (b) of this section shall be deemed to be adulterated in violation of section 402 of the Act.

[42 FR 14638, Mar. 15, 1977, as amended at 47 FR 11850, Mar. 19, 1982]

§ 181.33 Sodium nitrate and potassium nitrate.

Sodium nitrate and potassium nitrate are subject to prior sanctions issued by the U.S. Department of Agriculture for use as sources of nitrite, with or without sodium or potassium nitrite, in the production of cured red meat products and cured poultry products.

[48 FR 1705, Jan. 14, 1983]

§ 181.34 Sodium nitrite and potassium nitrite.

Sodium nitrite and potassium nitrite are subject to prior sanctions issued by the U.S. Department of Agriculture for use as color fixatives and preservative agents, with or without sodium or potassium nitrate, in the curing of red meat and poultry products.

[48 FR 1705, Jan. 14, 1983]

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.
182.1 Substances that are generally recognized as safe.

Sec.
182.10 Spices and other natural seasonings and flavorings.
182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).
182.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.
182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.
182.60 Synthetic flavoring substances and adjuvants.
182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.
182.90 Substances migrating to food from paper and paperboard products.
182.99 Adjuvants for pesticide chemicals.

Subpart B—Multiple Purpose GRAS Food Substances

182.1033 Citric acid.
182.1045 Glutamic acid.
182.1047 Glutamic acid hydrochloride.
182.1057 Hydrochloric acid.
182.1073 Phosphoric acid.
182.1087 Sodium acid pyrophosphate.
182.1125 Aluminum sulfate.
182.1127 Aluminum ammonium sulfate.
182.1129 Aluminum potassium sulfate.
182.1131 Aluminum sodium sulfate.
182.1180 Caffeine.
182.1195 Calcium citrate.
182.1217 Calcium phosphate.
182.1235 Caramel.
182.1320 Glycerin.
182.1324 Glyceryl monostearate.
182.1480 Methylcellulose.
182.1500 Monoammonium glutamate.
182.1516 Monopotassium glutamate.
182.1625 Potassium citrate.
182.1711 Silica aerogel.
182.1745 Sodium carboxymethylcellulose.
182.1748 Sodium caseinate.
182.1751 Sodium citrate.
182.1778 Sodium phosphate.
182.1781 Sodium aluminum phosphate.
182.1810 Sodium tripolyphosphate.
182.1866 High fructose corn syrup.
182.1901 Triacetin.
182.1911 Triethyl citrate.

Subpart C—Anticaking Agents

182.2122 Aluminum calcium silicate.
182.2227 Calcium silicate.
182.2437 Magnesium silicate.
182.2727 Sodium aluminosilicate.
182.2729 Sodium calcium aluminosilicate, hydrated.
182.2906 Tricalcium silicate.

Sec.

Subpart D—Chemical Preservatives

182.3013 Ascorbic acid.
182.3041 Erythorbic acid.
182.3089 Sorbic acid.
182.3109 Thiodipropionic acid.
182.3149 Ascorbyl palmitate.
182.3169 Butylated hydroxyanisole.
182.3173 Butylated hydroxytoluene.
182.3189 Calcium ascorbate.
182.3225 Calcium sorbate.
182.3280 Dilauryl thiodipropionate.
182.3616 Potassium bisulfite.
182.3637 Potassium metabisulfite.
182.3640 Potassium sorbate.
182.3731 Sodium ascorbate.
182.3739 Sodium bisulfite.
182.3766 Sodium metabisulfite.
182.3795 Sodium sorbate.
182.3798 Sodium sulfite.
182.3862 Sulfur dioxide.
182.3890 Tocopherols.

Subpart E—Emulsifying Agents

182.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
182.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
182.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

Subpart F—Dietary Supplements

182.5013 Ascorbic acid.
182.5065 Linoleic acid.
182.5159 Biotin.
182.5191 Calcium carbonate.
182.5195 Calcium citrate.
182.5201 Calcium glycerophosphate.
182.5210 Calcium oxide.
182.5212 Calcium pantothenate.
182.5217 Calcium phosphate.
182.5223 Calcium pyrophosphate.
182.5245 Carotene.
182.5250 Choline bitartrate.
182.5252 Choline chloride.
182.5260 Copper gluconate.
182.5301 Ferric phosphate.
182.5304 Ferric pyrophosphate.
182.5306 Ferric sodium pyrophosphate.
182.5308 Ferrous gluconate.
182.5311 Ferrous lactate.
182.5315 Ferrous sulfate.
182.5370 Inositol.
182.5375 Iron reduced.
182.5431 Magnesium oxide.
182.5434 Magnesium phosphate.
182.5443 Magnesium sulfate.
182.5446 Manganese chloride.
182.5449 Manganese citrate.
182.5452 Manganese gluconate.
182.5455 Manganese glycerophosphate.

Sec.
182.5461 Manganese sulfate.
182.5464 Manganous oxide.
182.5530 Niacin.
182.5535 Niacinamide.
182.5580 D-Pantothenyl alcohol.
182.5628 Potassium glycerophosphate.
182.5676 Pyridoxine hydrochloride.
182.5695 Riboflavin.
182.5697 Riboflavin-5-phosphate.
182.5772 Sodium pantothenate.
182.5778 Sodium phosphate.
182.5875 Thiamine hydrochloride.
182.5878 Thiamine mononitrate.
182.5890 Tocopherols.
182.5892 *a*-Tocopherol acetate.
182.5930 Vitamin A.
182.5933 Vitamin A acetate.
182.5936 Vitamin A palmitate.
182.5945 Vitamin B_{12}.
182.5950 Vitamin D_2.
182.5953 Vitamin D_3.
182.5985 Zinc chloride.
182.5988 Zinc gluconate.
182.5991 Zinc oxide.
188.5994 Zinc stearate.
182.5997 Zinc sulfate.

Subpart G—Sequestrants

182.6033 Citric acid.
182.6085 Sodium acid phosphate.
182.6195 Calcium citrate.
182.6197 Calcium diacetate.
182.6203 Calcium hexametaphosphate.
182.6215 Monobasic calcium phosphate.
182.6285 Dipotassium phosphate.
182.6290 Disodium phosphate.
182.6386 Isopropyl citrate.
182.6511 Monoisopropyl citrate.
182.6625 Potassium citrate.
182.6751 Sodium citrate.
182.6757 Sodium gluconate.
182.6760 Sodium hexametaphosphate.
182.6769 Sodium metaphosphate.
182.6778 Sodium phosphate.
182.6787 Sodium pyrophosphate.
182.6789 Tetra sodium pyrophosphate.
182.6810 Sodium tripolyphosphate.
182.6851 Stearyl citrate.

Subpart H—Stabilizers

182.7255 Chondrus extract.

Subpart I—Nutrients

182.8013 Ascorbic acid.
182.8159 Biotin.
182.8195 Calcium citrate.
182.8201 Calcium glycerophosphate.
182.8217 Calcium phosphate.
182.8223 Calcium pyrophosphate.
182.8245 Carotene.
182.8250 Choline bitartrate.
182.8252 Choline chloride.
182.8301 Ferric phosphate.
Sec.
182.8304 Ferric pyrophosphate.
182.8306 Ferric sodium pyrophosphate.
182.8308 Ferrous gluconate.
182.8311 Ferrous lactate.
182.8315 Ferrous sulfate.
182.8375 Iron reduced.
182.8455 Manganese glycerophosphate.
182.8458 Manganese hypophosphite.
182.8628 Potassium glycerophosphate.
182.8778 Sodium phosphate.
182.8890 Tocopherols.
182.8892 *a*-Tocopherol acetate.
182.8985 Zinc chloride.
182.8988 Zinc gluconate.
182.8991 Zinc oxide.
182.8994 Zinc stearate.
182.8997 Zinc sulfate.

AUTHORITY: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055—1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.11.

SOURCE: 42 FR 14640, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 182.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generaly recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect

in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in this part. When the status of a substance has been reevaluated, it will be deleted from this part, and will be issued as a new regulation under the appropriate part, e.g., "affirmed as GRAS" under Part 184 or 186 of this chapter; "food additive regulation" under Parts 170 through 180 of this chapter; "interim food additive regulation" under Part 180 of this chapter; or "prohibited from use in food" under Part 189 of this chapter.

§ 182.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa herb and seed	Medicago sativa L.
All spice	Pimenta officinalis Lindl.
Ambrette seed	Hibiscus abelmoschus L.
Angelica	Angelica archangelica L. or other spp. of Angelica.
Angelica root	Do.
Angelica seed	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Anise, star	Illicium verum Hook. f.
Balm (lemon balm)	Melissa officinalis L.
Basil, bush	Ocimum minimum L.
Basil, sweet	Ocimum basilicum L.
Bay	Laurus nobilis L.
Calendula	Calendula officinalis L.
Camomile (chamomile), English or Roman	Anthemis nobilis L.
Camomile (chamomile), German or Hungarian	Matricaria chamomilla L.
Capers	Capparis spinosa L.
Capsicum	Capsicum frutescens L. or Capsicum annuum L.
Caraway	Carum carvi L.
Caraway, black (black cumin)	Nigella sativa L.
Cardamom (cardamon)	Elettaria cardamomum Maton.
Cassia, Chinese	Cinnamomum cassia Blume.
Cassia, Padang or Batavia	Cinnamomum burmanni Blume.
Cassia, Saigon	Cinnamomum loureirii Nees.
Cayenne pepper	Capsicum frutescens L. or Capsicum annuum L.
Celery seed	Apium graveolens L.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chives	Allium schoenoprasum L.
Cinnamon, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon, Chinese	Cinnamomum cassia Blume.
Cinnamon, Saigon	Cinnamomum loureirii Nees.
Clary (clary sage)	Salvia sclarea L.
Clover	Trifolium spp.
Coriander	Coriandrum sativum L.
Cumin (cummin)	Cuminum cyminum L.
Cumin, black (black caraway)	Nigella sativa L.
Elder flowers	Sambucus canadensis L.
Fennel, common	Foeniculum vulgare Mill.
Fennel, sweet (finocchio, Florence fennel)	Foeniculum vulgare Mill. var. dulce (DC.) Alex.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Ginger	Zingiber officinale Rosc.
Grains of paradise	Amomum melegueta Rosc.

Common name	Botanical name of plant source
Horehound (hoarhound)	Marrubium vulgare L.
Horseradish	Armoracia lapathifolia Gilib.
Hyssop	Hyssopus officinalis L.
Lavender	Lavandula officinalis Chaix
Linden flowers	Tilia spp.
Mace	Myristica fragrans Houtt.
Marigold, pot	Calendula officinalis L.
Marjoram, pot	Majorana onites (L.) Benth.
Marjoram, sweet	Majorana hortensis Moench.
Mustard, black or brown	Brassica nigra (L.) Koch.
Mustard, brown	Brassica juncea (L.) Coss.
Mustard, white or yellow	Brassica hirta Moench.
Nutmeg	Myristica fragrans Houtt.
Oregano (oreganum, Mexican oregano, Mexican sage, origan).	Lippia spp.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, cayenne	Capsicum frutescens L. or Capsicum annuum L.
Pepper, red	Do.
Pepper, white	Piper nigrum L.
Peppermint	Mentha piperita L.
Poppy seed	Papaver somniferum L.
Pot marigold	Calendula officinalis L.
Pot marjoram	Majorana onites (L.) Benth.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Savory, summer	Satureia hortensis L. (Satureja).
Savory, winter	Satureia montana L. (Satureja).
Sesame	Sesamum indicum L.
Spearmint	Mentha spicata L.
Star anise	Illicium verum Hook. f.
Tarragon	Artemisia dracunculus L.
Thyme	Thymus vulgaris L.
Thyme, wild or creeping	Thymus serpyllum L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Zedoary	Curcuma zedoaria Rosc.

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[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 3705, Jan. 27, 1978; 44 FR 3963, Jan. 19, 1979; 50 FR 21044, May 22, 1985]

§ 182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Ambrette (seed)	Hibiscus moschatus Moench.
Angelica root	Angelica archangelica L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Asafetida	Ferula assa-foetida L. and related spp. of Ferula.
Balm (lemon balm)	Melissa officinalis L.
Balsam of Peru	Myroxylon pereirae Klotzsch.
Basil	Ocimum basilicum L.
Bay leaves	Laurus nobilis L.
Bay (myrcia oil)	Pimenta racemosa (Mill.) J. W. Moore.

Common name	Botanical name of plant source
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Bois de rose	Aniba rosaeodora Ducke.
Cacao	Theobroma cacao L.
Camomile (chamomile) flowers, Hungarian	Matricaria chamomilla L.
Camomile (chamomile) flowers, Roman or English	Anthemis nobilis L.
Cananga	Cananga odorata Hook. f. and Thoms.
Capsicum	Capsicum frutescens L. and Capsicum annuum L.
Caraway	Carum carvi L.
Cardamom seed (cardamon)	Elettaria cardamomum Maton.
Carob bean	Ceratonia siliqua L.
Carrot	Daucus carota L.
Cascarilla bark	Croton eluteria Benn.
Cassia bark, Chinese	Cinnamomum cassia Blume.
Cassia bark, Padang or Batavia	Cinnamomum burmanni Blume.
Cassia bark, Saigon	Cinnamomum loureirii Nees.
Celery seed	Apium graveolens L.
Cherry, wild, bark	Prunus serotina Ehrh.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chicory	Cichorium intybus L.
Cinnamon bark, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon bark, Chinese	Cinnamomum cassia Blume.
Cinnamon bark, Saigon	Cinnamomum loureirii Nees.
Cinnamon leaf, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon leaf, Chinese	Cinnamomum cassia Blume.
Cinnamon leaf, Saigon	Cinnamomum loureirii Nees.
Citronella	Cymbopogon nardus Rendle.
Citrus peels	Citrus spp.
Clary (clary sage)	Salvia sclarea L.
Clover	Trifolium spp.
Coca (decocainized)	Erythroxylum coca Lam. and other spp. of Erythroxylum.
Coffee	Coffea spp.
Cola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Coriander	Coriandrum sativum L.
Cumin (cummin)	Cuminum cyminum L.
Curacao orange peel (orange, bitter peel)	Citrus aurantium L.
Cusparia bark	Galipea officinalis Hancock.
Dandelion	Taraxacum officinale Weber and T. laevigatum DC.
Dandelion root	Do.
Dog grass (quackgrass, triticum)	Agropyron repens (L.) Beauv.
Elder flowers	Sambucus canadensis L. and S. nigra L.
Estragole (esdragol, esdragon, tarragon)	Artemisia dracunculus L.
Estragon (tarragon)	Do.
Fennel, sweet	Foeniculum vulgare Mill.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Geranium, East Indian	Cymbopogon martini Stapf.
Geranium, rose	Pelargonium graveolens L'Her.
Ginger	Zingiber officinale Rosc.
Grapefruit	Citrus paradisi Macf.
Guava	Psidium spp.
Hickory bark	Carya spp.
Horehound (hoarhound)	Marrubium vulgare L.
Hops	Humulus lupulus L.
Horsemint	Monarda punctata L.
Hyssop	Hyssopus officinalis L.
Immortelle	Helichrysum augustifolium DC.
Jasmine	Jasminum officinale L. and other spp. of Jasminum.
Juniper (berries)	Juniperus communis L.
Kola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Laurel berries	Laurus nobilis L.
Laurel leaves	Laurus spp.
Lavender	Lavandula officinalis Chaix.
Lavender, spike	Lavandula latifolia Vill.
Lavandin	Hybrids between Lavandula officinalis Chaix and Lavandula latifolin Vill.
Lemon	Citrus limon (L.) Burm. f.
Lemon balm (see balm)	
Lemon grass	Cymbopogon citratus DC. and Cymbopogon flexuosus Stapf.
Lemon peel	Citrus limon (L.) Burm. f.
Lime	Citrus aurantifolia Swingle.
Linden flowers	Tilia spp.

Common name	Botanical name of plant source
Locust bean	Ceratonia siliqua L.
Lupulin	Humulus lupulus L.
Mace	Myristica fragrans Houtt.
Mandarin	Citrus reticulata Blanco.
Marjoram, sweet	Majorana hortensis Moench.
Maté	Ilex paraguariensis St. Hil.
Melissa (see balm)	
Menthol	Mentha spp.
Menthyl acetate	Do.
Molasses (extract)	Saccarum officinarum L.
Mustard	Brassica spp.
Naringin	Citrus paradisi Macf.
Neroli, bigarade	Citrus aurantium L.
Nutmeg	Myristica fragrans Houtt.
Onion	Allium cepa L.
Orange, bitter, flowers	Citrus aurantium L.
Orange, bitter, peel	Do.
Orange leaf	Citrus sinensis (L.) Osbeck.
Orange, sweet	Do.
Orange, sweet, flowers	Do.
Orange, sweet, peel	Do.
Origanum	Origanum spp.
Palmarosa	Cymbopogon martini Stapf.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, white	Do.
Peppermint	Mentha piperita L.
Peruvian balsam	Myroxylon pereirae Klotzsch.
Petitgrain	Citrus aurantium L.
Petitgrain lemon	Citrus limon (L.) Burm. f.
Petitgrain mandarin or tangerine	Citrus reticulata Blanco.
Pimenta	Pimenta officinalis Lindl.
Pimenta leaf	Pimenta officinalis Lindl.
Pipsissewa leaves	Chimaphila umbellata Nutt.
Pomegranate	Punica granatum L.
Prickly ash bark	Xanthoxylum (or Zanthoxylum) Americanum Mill. or Xanthoxylum clava-herculis L.
Rose absolute	Rosa alba L., Rosa centifolia L., Rosa damascena Mill., Rosa gallica L., and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose geranium	Pelargonium graveolens L'Her.
Rose leaves	Rosa spp.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Sage, Spanish	Salvia lavandulaefolia Vahl.
St. John's bread	Ceratonia siliqua L.
Savory, summer	Satureia hortensis L.
Savory, winter	Satureia montana L.
Schinus molle	Schinus molle L.
Sloe berries (blackthorn berries)	Prunus spinosa L.
Spearmint	Mentha spicata L.
Spike lavender	Lavandula latifolia Vill.
Tamarind	Tamarindus indica L.
Tangerine	Citrus reticulata Blanco.
Tarragon	Artemisia dracunculus L.
Tea	Thea sinensis L.
Thyme	Thymus vulgaris L. and Thymus zygis var. gracilis Boiss.
Thyme, white	Do.
Thyme, wild or creeping	Thymus serpyllum L.
Triticum (see dog grass)	
Tuberose	Polianthes tuberosa L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Violet flowers	Viola odorata L.
Violet leaves	Do.
Violet leaves absolute	Do.
Wild cherry bark	Prunus serotina Ehrh.

Common name	Botanical name of plant source
Ylang-ylang	Cananga odorata Hook. f. and Thoms.
Zedoary bark	Curcuma zedoaria Rosc.

[42 FR 14640, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 47 FR 29953, July 9, 1982; 48 FR 51613, Nov. 10, 1983; 50 FR 21043 and 21044, May 22, 1985]

§ 182.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.

Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Apricot kernel (persic oil)	Prunus armeniaca L.
Peach kernel (persic oil)	Prunus persica Sieb. et Zucc.
Peanut stearine	Arachis hypogaea L.
Persic oil (see apricot kernel and peach kernel)	
Quince seed	Cydonia oblonga Miller

[42 FR 14640, Mar. 15, 1977, as amended at 47 FR 47375, Oct. 26, 1982]

§ 182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

Certain other spices, seasonings, essential oils, oleoresins, and natural extracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Derivation
Ambergris	Physeter macrocephalus L.
Castoreum	Castor fiber L. and C. canadensis Kuhl
Civet (zibeth, zibet, zibetum)	Civet cats, Viverra civetta Schreber and Viverra zibetha Schreber
Cognac oil, white and green	Ethyl oenanthate, so-called
Musk (Tonquin musk)	Musk deer, Moschus moschiferus L.

§ 182.60 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Acetaldehyde (ethanal).
Acetoin (acetyl methylcarbinol).
Anethole (parapropenyl anisole).
Benzaldehyde (benzoic aldehyde).
N-Butyric acid (butanoic acid).
d- or *l*-Carvone (carvol).
Cinnamaldehyde (cinnamic aldehyde).
Citral (2,6-dimethyloctadien-2,6-*al*-8, geranial, neral).
Decanal (*N*-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde C-10).
Ethyl acetate.
Ethyl butyrate.
3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde).
Ethyl vanillin.
Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-*ol*).
Geranyl acetate (geraniol acetate).
Glycerol (glyceryl) tributyrate (tributyrin, butyrin).
Limonene (*d*-, *l*-, and *dl*-).
Linalool (linalol, 3,7-dimethyl-1,6-octadien-3-*ol*).
Linalyl acetate (bergamol).
Methyl anthranilate (methyl-2-aminobenzoate).
Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin).
Vanillin.

[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 47724, Oct. 17, 1978; 44 FR 3963, Jan. 19, 1979; 44 FR 20656, Apr. 6, 1979; 48 FR 51907, Nov. 15, 1983]

§ 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.

Substances migrating to food from cotton and cotton fabrics used in dry food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Beef tallow.
Carboxymethylcellulose.
Coconut oil, refined.
Cornstarch.
Gelatin.
Japan wax.
Lard.
Lard oil.
Oleic acid.
Peanut oil.
Potato starch.
Sodium acetate.
Sodium chloride.
Sodium silicate.
Sodium tripolyphosphate.
Soybean oil (hydrogenated).
Talc.
Tallow (hydrogenated).
Tallow flakes.
Tapioca starch.
Tetrasodium pyrophosphate.
Wheat starch.
Zinc chloride.

[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 11698, Mar. 21, 1978; 44 FR 28323, May 15, 1979; 45 FR 6085, Jan. 25, 1980; 47 FR 27807, 27814, June 25, 1982; 48 FR 51150, Nov. 7, 1983; 48 FR 51616, Nov. 10, 1983; 48 FR 51909, Nov. 15, 1983; 48 FR 52441, 52443, 52445, 52446, Nov. 18, 1983; 51 FR 16830, May 7, 1986; 51 FR 27171, July 30, 1986]

§ 182.90 Substances migrating to food from paper and paperboard products.

Substances migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Alum (double sulfate of aluminum and ammonium potassium, or sodium).
Aluminum hydroxide.
Aluminum oleate.
Aluminum palmitate.
Casein.
Cellulose acetate.
Cornstarch.
Corn sugar (sirup).
Diatomaceous earth filler.
Ethyl cellulose.
Ethyl vanillin.
Ferric sulfate.
Ferrous sulfate.
Glycerin.
Invert sugar.
Iron, reduced.
Mono- and digylcerides from glycerolysis of edible fats and oils.
Oleic acid.
Oxides of iron.
Potassium sorbate.
Silicon dioxides.
Sodium aluminate.
Sodium chloride.
Sodium hexametaphosphate.
Sodium hydrosulfite.
Sodium phosphoaluminate.
Sodium silicate.
Sodium sorbate.
Sodium tripolyphosphate.
Sorbitol.
Soy protein, isolated.
Starch, acid modified.
Starch, pregelatinized.
Starch, unmodified.
Sucrose.
Talc.
Vanillin.
Zinc hydrosulfite.
Zinc sulfate.

[42 FR 14640, Mar. 15, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting § 182.90, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 182.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.1001 (c) and (d), which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the Act.

Subpart B—Multiple Purpose GRAS Food Substances

§ 182.1033 Citric acid.

(a) *Product.* Citric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1045 Glutamic acid.

(a) *Product.* Glutamic acid.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1047 Glutamic acid hydrochloride.

(a) *Product.* Glutamic acid hydrochloride.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1057 Hydrochloric acid.

(a) *Product.* Hydrochloric acid.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing practice.

§ 182.1073 Phosphoric acid.

(a) *Product.* Phosphoric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1087 Sodium acid pyrophosphate.

(a) *Product.* Sodium acid pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1125 Aluminum sulfate.

(a) *Product.* Aluminum sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1127 Aluminum ammonium sulfate.

(a) *Product.* Aluminum ammonium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1129 Aluminum potassium sulfate.

(a) *Product.* Aluminum potassium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1131 Aluminum sodium sulfate.

(a) *Product.* Aluminum sodium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1180 Caffeine.

(a) *Product.* Caffeine.

(b) *Tolerance.* 0.02 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.

§ 182.1195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1235 Caramel.

(a) *Product.* Caramel.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1320 Glycerin.

(a) *Product.* Glycerin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1324 Glyceryl monostearate.

(a) *Product.* Glyceryl monostearate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1480 Methylcellulose.

(a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1500 Monoammonium glutamate.

(a) *Product.* Monoammonium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1516 Monopotassium glutamate.

(a) *Product.* Monopotassium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1711 Silica aerogel.

(a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of an anti-foaming agent in accordance with good manufacturing practice.

§ 182.1745 Sodium carboxymethylcellulose.

(a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25° C.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1748 Sodium caseinate.

(a) *Product.* Sodium caseinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1781 Sodium aluminum phosphate.

(a) *Product.* Sodium aluminum phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1866 High fructose corn syrup.

(a) *Product.* High fructose corn syrup is a sweet, nutritive saccharide mixture containing approximately 52 percent (dry weight) glucose, 43 percent (dry weight) fructose, and 5 percent (dry weight) other saccharides. It is prepared as a clear aqueous solution from high dextrose equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose utilizing an insoluble glucose isomerase enzyme preparation described in § 184.1372 of this chapter.

(b) *Limitations, restrictions, or explanations.* This substance is generally recognized as safe when used in food as a nutritive carbohydrate sweetener at levels not to exceed current good manufacturing practice.

[48 FR 5719, Feb. 8, 1983]

§ 182.1901 Triacetin.

(a) *Product.* Triacetin (glyceryl triacetate).

(b) *Conditions of use* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1911 Triethyl citrate.

(a) *Product.* Triethyl citrate.

(b) *Tolerance.* 0.25 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

Subpart C—Anticaking Agents

§ 182.2122 Aluminum calcium silicate.

(a) *Product.* Aluminum calcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2227 Calcium silicate.

(a) *Product.* Calcium silicate.

(b) *Tolerance.* 2 percent and 5 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used at levels not exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing practice.

§ 182.2437 Magnesium silicate.

(a) *Product.* Magnesium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2727 Sodium aluminosilicate.

(a) *Product.* Sodium aluminosilicate (sodium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2729 Sodium calcium aluminosilicate, hydrated.

(a) *Product.* Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2906 Tricalcium silicate.

(a) *Product.* Tricalcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

Subpart D—Chemical Preservatives

§ 182.3013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3041 Erythorbic acid.

(a) *Product.* Erythorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3089 Sorbic acid.

(a) *Product.* Sorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3109 Thiodipropionic acid.

(a) *Product.* Thiodipropionic acid.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3149 Ascorbyl palmitate.

(a) *Product.* Ascorbyl palmitate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3169 Butylated hydroxyanisole.

(a) *Product.* Butylated hydroxyanisole.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3173 Butylated hydroxytoluene.

(a) *Product.* Butylated hydroxytoluene.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3189 Calcium ascorbate.

(a) *Product.* Calcium ascorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3225 Calcium sorbate.

(a) *Product.* Calcium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3280 Dilauryl thiodipropionate.

(a) *Product.* Dilauryl thiodipropionate.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3616 Potassium bisulfite.

(a) *Product.* Potassium bisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986]

§ 182.3637 Potassium metabisulfite.

(a) *Product.* Potassium metabisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986]

§ 182.3640 Potassium sorbate.

(a) *Product.* Potassium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3731 Sodium ascorbate.

(a) *Product.* Sodium ascorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3739 Sodium bisulfite.

(a) *Product.* Sodium bisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986]

§ 182.3766 Sodium metabisulfite.

(a) *Product.* Sodium metabisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986]

§ 182.3795 Sodium sorbate.

(a) *Product.* Sodium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3798 Sodium sulfite.

(a) *Product.* Sodium sulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25026, July 9, 1986]

§ 182.3862 Sulfur dioxide.

(a) *Product.* Sulfur dioxide.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25026, July 9, 1986]

§ 182.3890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart E—Emulsifying Agents

§ 182.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(a) *Product.* Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart F—Dietary Supplements[1]

§ 182.5013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5065 Linoleic acid.

(a) *Product.* Linoleic acid prepared from edible fats and oils and free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5159 Biotin.

(a) *Product.* Biotin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5191 Calcium carbonate.

(a) *Product.* Calcium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5201 Calcium glycerophosphate.

(a) *Product.* Calcium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5210 Calcium oxide.

(a) *Product.* Calcium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5212 Calcium pantothenate.

(a) *Product.* Calcium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5245 Carotene.

(a) *Product.* Carotene.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5260 Copper gluconate.

(a) *Product.* Copper gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice.

[49 FR 24119, June 12, 1984]

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[1] Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.

§ 182.5301 Ferric phosphate.

(a) *Product.* Ferric phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5304 Ferric pyrophosphate.

(a) *Product.* Ferric pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5306 Ferric sodium pyrophosphate.

(a) *Product.* Ferric sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5308 Ferrous gluconate.

(a) *Product.* Ferrous gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5311 Ferrous lactate.

(a) *Product.* Ferrous lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5315 Ferrous sulfate.

(a) *Product.* Ferrous sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5370 Inositol.

(a) *Product.* Inositol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5375 Iron reduced.

(a) *Product.* Iron reduced.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5434 Magnesium phosphate.

(a) *Product.* Magnesium phosphate (di- and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5443 Magnesium sulfate.

(a) *Product.* Magnesium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5446 Manganese chloride.

(a) *Product.* Manganese chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5449 Manganese citrate.

(a) *Product.* Manganese citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5452 Manganese gluconate.

(a) *Product.* Manganese gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5455 Manganese glycerophosphate.

(a) *Product.* Manganese glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5461 Manganese sulfate.

(a) *Product.* Manganese sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5464 Manganous oxide.

(a) *Product.* Manganous oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5530 Niacin.

(a) *Product.* Niacin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5535 Niacinamide.

(a) *Product.* Niacinamide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5580 D-Pantothenyl alcohol.

(a) *Product.* D-Pantothenyl alcohol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5622 Potassium chloride.

(a) *Product.* Potassium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice. Preparations containing amounts equal to or greater than 100 milligrams of potassium per tablet or capsule, or 20 milligrams of potassium per milliliter, are drugs subject to the provisions of § 201.306 of this chapter.

[42 FR 14640, Mar. 15, 1977, as amended at 48 FR 51614, Nov. 10, 1983]

§ 182.5628 Potassium glycerophosphate.

(a) *Product.* Potassium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5676 Pyridoxine hydrochloride.

(a) *Product.* Pyridoxine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5695 Riboflavin.

(a) *Product.* Riboflavin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5697 Riboflavin-5-phosphate.

(a) *Product.* Riboflavin-5-phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5772 Sodium pantothenate.

(a) *Product.* Sodium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5875 Thiamine hydrochloride.

(a) *Product.* Thiamine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5878 Thiamine mononitrate.

(a) *Product.* Thiamine mononitrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5892 α-Tocopherol acetate.

(a) *Product.* α-Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5930 Vitamin A.

(a) *Product.* Vitamin A.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5933 Vitamin A acetate.

(a) *Product.* Vitamin A acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5936 Vitamin A palmitate.

(a) *Product.* Vitamin A palmitate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5945 Vitamin B_{12}.

(a) *Product.* Vitamin B_{12}.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5950 Vitamin D_2.

(a) *Product.* Vitamin D_2.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5953 Vitamin D_3.

(a) *Product.* Vitamin D_3.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5985 Zinc chloride.

(a) *Product.* Zinc chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5988 Zinc gluconate.

(a) *Product.* Zinc gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5991 Zinc oxide.

(a) *Product.* Zinc oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5997 Zinc sulfate.

(a) *Product.* Zinc sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart G—Sequestrants [1]

§ 182.6033 Citric acid.

(a) *Product.* Citric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6085 Sodium acid phosphate.

(a) *Product.* Sodium acid phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6197 Calcium diacetate.

(a) *Product.* Calcium diacetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

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[1] For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

§ 182.6203 Calcium hexametaphosphate.

(a) *Product.* Calcium hexametaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6215 Monobasic calcium phosphate.

(a) *Product.* Monobasic calcium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6285 Dipotassium phosphate.

(a) *Product.* Dipotassium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6290 Disodium phosphate.

(a) *Product.* Disodium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6386 Isopropyl citrate.

(a) *Product.* Isopropyl citrate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.02 percent in accordance with good manufacturing practice.

§ 182.6511 Monoisopropyl citrate.

(a) *Product.* Monoisopropyl citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6757 Sodium gluconate.

(a) *Product.* Sodium gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6760 Sodium hexametaphosphate.

(a) *Product.* Sodium hexametaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6769 Sodium metaphosphate.

(a) *Product.* Sodium metaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6787 Sodium pyrophosphate.

(a) *Product.* Sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6789 Tetra sodium pyrophosphate.

(a) *Product.* Tetra sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6851 Stearyl citrate.

(a) *Product.* Stearyl citrate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.15 percent in accordance with good manufacturing practice.

Subpart H—Stabilizers

§ 182.7255 Chondrus extract.

(a) *Product.* Chondrus extract (carrageenin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart I—Nutrients

SOURCE: 45 FR 58838, Sept. 5, 1980, unless otherwise noted.

§ 182.8013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8159 Biotin.

(a) *Product.* Biotin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8201 Calcium glycerophosphate.

(a) *Product.* Calcium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8245 Carotene.

(a) *Product.* Carotene.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8301 Ferric phosphate.

(a) *Product.* Ferric phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8304 Ferric pyrophosphate.

(a) *Product.* Ferric pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8306 Ferric sodium pyrophosphate.

(a) *Product.* Ferric sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8308 Ferrous gluconate.

(a) *Product.* Ferrous gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8311 Ferrous lactate.

(a) *Product.* Ferrous lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8315 Ferrous sulfate.

(a) *Product.* Ferrous sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8375 Iron reduced.

(a) *Product.* Iron reduced.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8455 Manganese glycerophosphate.

(a) *Product.* Manganese glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8458 Manganese hypophosphite.

(a) *Product.* Manganese hypophosphite.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8628 Potassium glycerophosphate.

(a) *Product.* Potassium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8892 α-Tocopherol acetate.

(a) *Product.* α-Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8985 Zinc chloride.

(a) *Product.* Zinc chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8988 Zinc gluconate.

(a) *Product.* Zinc gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8991 Zinc oxide.

(a) *Product.* Zinc oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8997 Zinc sulfate.

(a) *Product.* Zinc sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

Sec.

Subpart B—Listing of Specific Substances Affirmed as GRAS

184.1005 Acetic acid.
184.1007 Aconitic acid.
184.1009 Adipic acid.
184.1011 Alginic acid.
184.1021 Benzoic acid.
184.1025 Caprylic acid.
184.1027 Mixed carbohydrase and protease enzyme product.
184.1061 Lactic acid.
184.1065 Linoleic acid.
184.1069 Malic acid.
184.1077 Potassium acid tartrate.
184.1081 Propionic acid.
184.1090 Stearic acid.
184.1091 Succinic acid.
184.1095 Sulfuric acid.
184.1097 Tannic acid.
184.1099 Tartaric acid.
184.1115 Agar-agar.
184.1120 Brown algae.
184.1121 Red aslgae.
184.1133 Ammonium alginate.
184.1135 Ammonium bicarbonate.
184.1137 Ammonium carbonate.
184.1138 Ammonium chloride.
184.1139 Ammonium hydroxide.
184.1141a Ammonium phosphate, monobasic.
184.1141b Ammonium phosphate, dibasic.
184.1143 Ammonium sulfate.
184.1155 Bentonite.
184.1157 Benzoyl peroxide.
184.1165 n-Butane and iso-butane.
184.1185 Calcium acetate.
184.1187 Calcium alginate.
184.1191 Calcium carbonate.
184.1193 Calcium chloride.
184.1199 Calcium gluconate.
184.1205 Calcium hydroxide.
184.1206 Calcium iodate.
184.1207 Calcium lactate.
184.1210 Calcium oxide.
184.1212 Calcium pantothenate.
184.1221 Calcium propionate.
184.1229 Calcium stearate.
184.1230 Calcium sulfate.
184.1240 Carbon dioxide.
184.1257 Clove and its derivatives.
184.1259 Cocoa butter substitute primarily from palm oil.
184.1260 Copper gluconate.
184.1261 Copper sulfate.
184.1262 Corn silk and corn silk extract.
184.1265 Cuprous iodide.
184.1271 L-Cysteine.
184.1272 L-Cysteine monohydrochloride.
184.1277 Dextrin.
184.1278 Diacetyl.
184.1282 Dill and its derivatives.
184.1293 Ethyl alcohol.
184.1295 Ethyl formate.
184.1317 Garlic and its derivatives.

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184.1318 Glucono delta-lactone.
184.1321 Corn gluten.
184.1322 Wheat gluten.
184.1330 Acacia (gum arabic).
184.1333 Gum ghatti.
184.1339 Guar gum.
184.1343 Locust (carob) bean gum.
184.1349 Karaya gum (sterculia gum).
184.1351 Gum tragacanth.
184.1355 Helium.
184.1366 Hydrogen peroxide.
184.1370 Inositol.
184.1372 Insoluble glucose isomerase enzyme preparations.
184.1388 Lactase enzyme preparation from Kluyveromyces lactis.
184.1400 Lecithin.
184.1408 Licorice and licorice derivatives.
184.1409 Ground limestone.
184.1425 Magnesium carbonate.
184.1426 Magnesium chloride.
184.1428 Magnesium hydroxide.
184.1431 Magnesium oxide.
184.1434 Magnesium phosphate.
184.1440 Magnesium stearate.
184.1443 Magnesium sulfate.
184.1444 Maltodextrin.
184.1445 Malt syrup (malt extract).
184.1446 Manganese chloride.
184.1449 Manganese citrate.
184.1452 Manganese gluconate.
184.1461 Manganese sulfate.
184.1490 Methylparaben.
184.1530 Niacin.
184.1535 Niacinamide.
184.1537 Nickel.
184.1540 Nitrogen.
184.1545 Nitrous oxide.
184.1553 Peptones.
184.1555 Rapeseed oil.
184.1560 Ox bile extract.
184.1563 Ozone.
184.1585 Papain.
184.1588 Pectins.
184.1610 Potassium alginate.
184.1613 Potassium bicarbonate.
184.1619 Potassium carbonate.
184.1622 Potassium chloride.
184.1631 Potassium hydroxide.
184.1634 Potassium iodide.
184.1635 Potassium iodate.
184.1643 Potassium sulfate.
184.1655 Propane.
184.1660 Propyl gallate.
184.1666 Propylene glycol.
184.1670 Propylparaben.
184.1676 Pyridoxine hydrochloride.
184.1685 Rennet (animal-derived).
184.1695 Riboflavin.
184.1697 Riboflavin-5'-phosphate (sodium).
184.1698 Rue.
184.1699 Oil of rue.
184.1721 Sodium acetate.
184.1724 Sodium alginate.
184.1733 Sodium benzoate.

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184.1736 Sodium bicarbonate.
184.1742 Sodium carbonate.
184.1754 Sodium diacetate.
184.1763 Sodium hydroxide.
184.1764 Sodium hypophosphite.
184.1769a Sodium metasilicate.
184.1792 Sodium sesquicarbonate.
184.1784 Sodium propionate.
184.1801 Sodium tartrate.
184.1804 Sodium potassium tartrate.
184.1807 Sodium thiosulfate.
184.1835 Sorbitol.
184.1845 Stannous chloride (anhydrous and dihydrated).
184.1848 Starter distillate.
184.1875 Thiamine hydrochloride.
184.1878 Thiamine mononitrate.
184.1890 α-Tocopherols.
184.1923 Urea.
184.1930 Vitamin A.
184.1945 Vitamin B_{12}.
184.1950 Vitamin D.
184.1973 Beeswax (yellow and white).
184.1976 Candelilla wax.
184.1978 Carnauba wax.
184.1979 Whey.
184.1979a Reduced lactose whey.
184.1979b Reduced minerals whey.
184.1979c Whey protein concentrate.
184.1983 Bakers yeast extract.
184.1984 Zein.

AUTHORITY: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

SOURCE: 42 FR 14653, Mar 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this part shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as GRAS. Ingredients affirmed as GRAS in this part are also GRAS as indirect human food ingredients, subject to any limitations prescribed in Parts 174, 175, 176, 177, 178 or § 179.45 of this chapter of in Part 186 of this chapter. The purity specifications in this part do not apply when the ingredient is used in indirect applications. However, when used in indirect applications, the ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(b) Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practice. For the purpose of this part, current good manufacturing practice includes the requirements that a direct human food ingredient be of appropriate food grade; that it be prepared and handled as a food ingredient; and that the quantity of the ingredient added to food does not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect in food.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraph (b), (c), and (d) of this section. When the Food and Drug Administration (FDA) determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the ingredient, one or more of these limited conditions of use, which may include the category of food(s), the technical effect(s) or functional use(s) of the ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, that use of the ingredient may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an

independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with § 170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, without a general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(d) The listing of more than one ingredient to produce the same technological effect does not authorize use of a combination of two or more ingredients to accomplish the same technological effect in any one food at a combined level greater than the highest level permitted for one of the ingredients.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under Part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in Part 101 of this chapter.

(2) A statement of concentration of the ingredient in any intermediate mix; or other information to permit a food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice guidelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 184.1005 Acetic acid.

(a) Acetic acid ($C_2H_4O_2$, CAS Reg. No. 64-19-7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a curing and pickling agent as defined in

§ 170.3(o)(5) of this chapter; flavor enhancer as defined in § 170.3(o)(11) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level as served, of 0.25 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.8 percent for cheeses as defined in § 170.3(n)(5) of this chapter and dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.5 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 9.0 percent for condiments and relishes as defined in § 170.3(n)(8) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 3.0 percent for gravies and sauces as defined in § 170.3(n)(24) of this chapter; 0.6 percent for meat products as defined in § 170.3(n)(29) of this chapter; and 0.15 percent or less for all other food categories. The ingredient may also be used in boiler water additives at levels not to exceed current good manufacturing practice.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27814, June 25, 1982]

§ 184.1007 Aconitic acid.

(a) Aconitic acid (1,2,3-propenetricarboxylic acid ($C_6H_6O_6$), CAS Reg. No. 000499-12-7) occurs in the leaves and tubers of *Aconitum napellus* L. and other *Ranunculaceae*. Transaconitic acid can be isolated during sugarcane processing, by precipitation as the calcium salt from cane sugar or molasses. It may be synthesized by sulfuric acid dehydration of citric acid, but not by the methanesulfonic acid method.

(b) The ingredient meets the following specifications:

(1) *Assay*. Not less than 98.0 percent of $C_3H_3(COOH)_3$, using the "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, test for citric acid, which is incorporated by reference, and a molecular weight of 174.11. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Melting point*. Not less than 195° C and the determination results in decomposition of aconitic acid.

(3) *Heavy metals (as Pb)*. Not more than 10 parts per million.

(4) *Arsenic (as As)*. Not more than 3 parts per million.

(5) *Oxalate*. Passes test.

(6) *Readily carbonizable substances*. Passes "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, test for citric acid, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(7) *Residue on ignition*. Not more than 0.1 percent as determined by "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, test for citric acid, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

The substance should have infrared absorption bands at 3030, 2630, 1720, 1430, 1300, 1240, 910, 860, 780, and 750 cm^{-1}. Also, an aqueous solution of the substance should have major absorption peaks at 411 and 432 nanometers with little or no absorption at 389 nanometers.

(c) The ingredient is used as a flavoring substance and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food, in accordance with § 184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.003 percent for baked goods as defined in § 170.3(n)(1) of this chapter, 0.002 percent for alcoholic beverages as defined in § 170.3(n)(2) of this chapter, 0.0015 percent for frozen dairy products as defined in § 170.3(n)(20) of this chapter, 0.0035 percent for soft candy as defined in § 170.3(n)(38) of this chapter, and

0.0005 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 47724, Oct. 17, 1978, as amended at 49 FR 5610, Feb. 14, 1984]

§ 184.1009 Adipic acid.

(a) Adipic acid ($C_6H_{10}O_4$ CAS Reg. No. 00124-04-9) is also known as 1, 4-butanedicarboxylic acid or hexanedioic acid. It is prepared by nitric acid oxidation of cyclohexanol or cyclohexanone or a mixture of the two.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 11, which is incorporated by reference (copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and the following additional specifications:

(1) The adipic acid is converted to its corresponding amide. The amide is purified by recrystallization from water or aqueous ethanol. The melting range of the amide is 219° to 220° C.

(2) The adipic acid is converted to its corresponding *bis-p-p*-bromophenacyl ester. The ester is purified by recrystallization from ethanol. The melting range of the ester is 153° to 154° C.

(c) The ingredient is used as a flavoring agent as defined in § 170.3(o)(12) of this chapter; leavening agent as defined in § 170.3(o)(17) of this chapter; and pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 0.05 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.005 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; 5.0 percent for condiments and relishes as defined in § 170.3(n)(8) of this chapter; 0.45 percent for dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.3 percent for fats and oil as defined in § 170.3(n)(12) of this chapter; 0.0004 percent for frozen dairy desserts as defined in § 170.3(n)(20) of this chapter; 0.55 percent for gelatin and puddings as defined in § 170.3(n)(22) of this chapter; 0.1 percent for gravies as defined in § 170.3(n)(24) of this chapter; 0.3 percent for meat products as defined in § 170.3(n)(29) of this chapter; 1.3 percent for snack foods as defined in § 170.3(n)(37) of this chapter; and 0.02 percent or less for all other food categories.

(e) Prior sanctions for adipic acid different from the uses established in this section do not exist or have been waived.

[47 FR 27810, June 25, 1982]

§ 184.1011 Alginic acid.

(a) Alginic acid is a colloidal, hydrophilic polysaccharide obtained from certain brown algae by alkaline extraction.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 13, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Soup and soup mixes, § 170.3(n)(40) of this chapter	Not to exceed current good manufacturing practice	Emulsifier, emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 47375, Oct. 26, 1982]

§ 184.1021 Benzoic acid.

(a) Benzoic acid is the chemical benzenecarboxylic acid ($C_7H_6O_2$), occurring in nature in free and combined forms. Among the foods in which benzoic acid occurs naturally are cranberries, prunes, plums, cinnamon, ripe cloves, and most berries. Benzoic acid is manufactured by treating molten phthalic anhydride with steam in the presence of a zinc oxide catalyst, by the hydrolysis of benzotrichloride, or by the oxidation of toluene with nitric acid or sodium bichromate or with air in the presence of a transition metal salt catalyst.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS).

(e) Prior sanctions for this ingredient different from those uses established in this section, or different from that set forth in Part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 184.1025 Caprylic acid.

(a) Caprylic acid [$CH_3(CH_2)_6COOH$, CAS Reg. No. 124-07-2] is the chemical name for octanoic acid. It is considered to be a short or medium chain fatty acid. It occurs normally in various foods and is commercially prepared by oxidation of *n*-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 207, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in foods in accordance with § 184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practices result in maximum levels, as served, of: 0.013 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.04 percent for cheeses as defined in § 170.3(n)(5) of this chapter; 0.005 percent for fats and oils as defined in § 170.3(n)(12) of this chapter, for frozen dairy desserts as defined in § 170.3(n)(20) of this chapter, for gelatins and puddings as defined in § 170.3(n)(22) of this chapter, for meat products as defined in § 170.3(n)(29) of this chapter, and for soft candy as defined in § 170.3(n)(38) of this chapter; 0.016 percent for snack foods as defined in § 170.3(n)(37) of this chapter; and 0.001 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 19843, May 9, 1978, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1027 Mixed carbohydrase and protease enzyme product.

(a) Mixed carbohydrase and protease enzyme product is an enzyme preparation that includes carbohydrase and protease activity. It is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic strain of *B. licheniformis*.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 107, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, to hydrolyze proteins or carbohydrates.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: alcoholic beverages, as defined in § 170.3(n)(2) of this chapter, candy, nutritive sweeteners, and protein hydrolyzates.

[48 FR 240, Jan. 4, 1983]

§ 184.1061 Lactic acid.

(a) Lactic acid ($C_3H_6O_3$, CAS Reg. Nos.: DL mixture, 598-82-3; L-isomer, 79-33-4; D-isomer, 10326-41-7), the chemical 2-hydroxypropanoic acid, occurs naturally in several foods. It is produced commercially either by fermentation of carbohydrates such as glucose, sucrose, or lactose, or by a procedure involving formation of lactonitrile from acetaldehyde and hydrogen cyanide and subsequent hydrolysis to lactic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 159, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter; a curing and pickling agent as defined in § 170.3(o)(5) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; and a solvent and vehicle as defined in § 170.3(o)(27) of this chapter.

(2) The ingredient is used in food, except in infant foods and infant formulas, at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 35367, Sept. 7, 1984]

§ 184.1065 Linoleic acid.

(a) Linoleic acid ((Z, Z)-9, 12-octadecadienoic acid ($C_{17}H_{31}COOH$) (CAS Reg. No. 60-33-3)), a straight chain unsaturated fatty acid with a molecular weight of 280.5, is a colorless oil at room temperature. Linoleic acid may be prepared from edible fats and oils by various methods including hydrolysis and saponification, the Twitchell method, low pressure splitting with catalyst, continuous high pressure counter current splitting, and medium pressure autoclave splitting with catalyst.

(b) FDA is developing food-grade specifications for linoleic acid in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use. The ingredient must also meet the specifications in § 172.860(b) of this chapter.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 48534, Dec. 13, 1984]

§ 184.1069 Malic acid.

(a) Malic acid ($C_4H_6O_5$, CAS Reg. No. of L-form 97-67-6, CAS Reg. No. of DL-form 617-48-1) is the common name for 1-hydroxy-1, 2-ethanedicarboxylic acid. L (+) malic acid, referred to as L-malic acid, occurs naturally in various foods. Racemic DL-malic acid does not occur naturally. It is made commercially by hydration of fumaric acid or maleic acid.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 183-184, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredients are used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, and pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredients are used in food, except baby food, at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 3.4 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; 3.0 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 0.8 percent for gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; 6.9 percent for hard candy as defined in § 170.3(n)(25) of this chapter; 2.6 percent for jams and jellies as defined in § 170.3(n)(28) of this chapter; 3.5 percent for processed fruits and fruit juices as defined in § 170.3(n)(35) of this chapter; 3.0 percent for soft candy as defined in § 170.3(n)(38) of this chapter; and 0.7 percent for all other food categories.

(e) Prior sanctions for malic acid different from the uses established in this section do not exist or have been waived.

[44 FR 20656, Apr. 6, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1077 Potassium acid tartrate.

(a) Potassium acid tartrate ($C_4H_5KO_6$, CAS Reg. No. 868-14-4) is the potassium acid salt of L-(+)-tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), P. 238, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20403.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking agent as defined in § 170.3(o)(1) of this chapter; an antimicrobial agent as defined in § 170.3(o)(2) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; A pH control agent as defined in § 170.3(o)(23) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; and a surface-active agent as

defined in § 170.3(o)(29) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins and puddings as defined in § 170.3(n)(22) of this chapter; hard candy as defined in § 170.3(n)(25) of this chapter; jams and jellies as defined in § 170.3(n)(28) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52446, Nov. 18, 1983]

§ 184.1081 Propionic acid.

(a) Propionic acid ($C_3H_6O_2$, CAS Reg. No. 79-09-4) is an oily liquid having a slightly pungent, rancid odor. It is manufactured by chemical synthesis or by bacterial fermentation.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 254, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter and a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13141, Apr. 3, 1984]

§ 184.1090 Stearic acid.

(a) Stearic acid ($C_{18}H_{36}O_2$, CAS Reg. No. 57-11-4) is a white to yellowish white solid. It occurs naturally as a glyceride in tallow and other animal or vegetable fats and oils and is a principal constituent of most commercially hydrogenated fats. It is produced commercially from hydrolyzed tallow derived from edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 313, which is incorporated by reference, and the requirements of § 172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52445, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1091 Succinic acid.

(a) Succinic acid ($C_4H_6O_4$, CAS Reg. No. 110-15-6), also referred to as amber acid and ethylenesuccinic acid, is the chemical 1,4-butanedioic acid. It is commercially prepared by hydrogenation of maleic or fumaric acid. It can also be produced by aqueous alkali or acid hydrolysis of succinonitrile.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 314-315, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter and pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.084 percent in condiments and relishes as defined in § 170.3(n)(8) of this chapter and 0.0061 percent in meat products as defined in § 170.3(n)(29) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[44 FR 20657, Apr. 6, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1095 Sulfuric acid.

(a) Sulfuric acid (H_2SO_4, CAS Reg. No. 7664-93-9), also known as oil of vitriol, is a clear, colorless, oily liquid. It is prepared by reacting sulfur dioxide (SO_2) with oxygen and mixing the resultant sulfur trioxide (SO_3) with water, or by reacting nitric oxide (NO) with sulfur dioxide and water.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 317-318, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.014 percent for alcoholic beverages as defined in § 170.3(n)(2) of this chapter and 0.0003 percent for cheeses as defined in § 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6085, Jan. 25, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1097 Tannic acid.

(a) Tannic acid (CAS Reg. No. 1401-55-4), or hydrolyzable gallotannin, is a complex polyphenolic organic structure that yields gallic acid and either glucose or quinic acid as hydrolysis products. It is a yellowish-white to light brown substance in the form of an amorphous, bulky powder, glistening scales, or spongy masses. It is also ordorless, or has a faint characteristic odor, and has an astringent taste. Tannic acid is obtained by solvent extraction of nutgalls or excrescences that form on the young twigs of *Quercus infectoria Oliver* and related species of *Quercus*. Tannic acid is also obtained by solvent extraction of the seed pods of Tara (*Caesalpinia spinosa*) or the nutgalls of various sumac species, including *Rhus semialata*, *R. coriaria*, *R. galabra*, and *R. typhia*.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 319, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c)(1) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.01	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter
Alcoholic beverages, § 170.3(n)(2) of this chapter	0.015	Flavor enhancer, § 170.3(o)(11) of this chapter, flavoring agent and adjuvant, § 170.3(o)(12) of this chapter, processing aid, § 170.3(o)(24) of this chapter
Nonalcoholic beverages and beverage bases, § 170.3(n)(3) of this chapter and for gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter	0.005	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter, pH control agent, § 170.3(o)(23) of this chpater
Frozen dairy desserts and mixes, § 170.3(n)(20) of this chapter and for soft candy, § 170.3(n)(38) of this chapter	0.04	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter
Hard candy and cough drops, §170.3(n)(25) of this chapter	0.013	Do
Meat products, § 170.3(n)(29) of this chapter	0.001	Do

(2) Tannic acid may be used in rendered animal fat in accordance with 9 CFR 318.7.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 21043, May 22, 1985]

§ 184.1099 Tartaric acid.

(a) Food grade tartaric acid ($C_4H_6O_6$, CAS Reg. No. 87-69-4) has the L configuration. The L form of tartaric acid is dextrorotatory in solution and is also known as L-(+)-tartaric acid. Tartaric acid occurs as colorless or translucent crystals or as a white, crystalline powder. It is odorless and has an acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), P. 320, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a firming agent as defined in § 170.3(o)(10) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent as defined in § 170.3(o)(12) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52447, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1115 Agar-agar.

(a) Agar-agar (CAS Reg. No. PM 9002-18-0) is a dried, hydrophyllic, colloidal polysaccharide extracted from one of a number of related species of red algae (class *Rhodophyceae*).

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 11, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used in food in accordance with § 184.1(b)(2) under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Foods (as served)	Percent	Functions
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.8	Drying agent, § 170.3(o)(7) of this chapter, flavoring agent, § 170.3(o)(12) of this chapter stabilizer, thickener, § 170.3(o)(28) of this chapter
Confections and frostings, § 170.3(n)(9) of this chapter	2.0	Flavoring agent, § 170.3(o)(12) of this chapter, stabilizer, thickener, § 170.3(o)(28) of this chapter, surface finisher, § 170.3(o)(30) of this chapter
Soft candy, § 170.3(n)(38) of this chapter	1.2	Stabilizer and thickener, § 170.3(o)(28) of this chapter
All other food categories	.25	Flavoring agent § 170.3(o)(12) of this chapter, formulation aid, § 170.3(o)(14) of this chapter, humectant, § 170.3(o)(16) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[44 FR 19391, Apr. 3, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1120 Brown algae.

(a) Brown algae are seaweeds of the species *Analipus japonicus, Eisenia bicyclis, Hizikia fusiforme, Kjellmaniella gyrata, Laminaria angustata, Laminaria claustonia, Laminaria digitata, Laminaria japonica, Laminaria longicruris, Laminaria longissima, Laminaria ochotensis, Laminaria saccharina, Macrocystis pyrifera, Petalonia fascia, Scytosiphon lomentaria* and *Undaria pinnatifida.* They are harvested principally in coastal waters of the northern Atlantic and Pacific oceans. The material is dried and ground or chopped for use in food.

(b) The ingredient meets the specifications for kelp in the Food Chemicals Codex, 3d Ed. (1981), p. 157, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L ST. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Spices, seasonings, and flavorings, § 170.3(n)(26) of this chapter	Not to exceed current good manufacturing practice	Flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 47376, Oct. 26, 1982]

§ 184.1121 Red algae.

(a) Red algae are seaweeds of the species *Gloiopeltis furcata, Porphyra crispata, Porphyra deutata, Porphyra perforata, Porphyra suborbiculata, Porphyra tenera* and *Rhodymenia palmata. Porphyra* and *Rhodymenia* are harvested principally along the coasts of Japan, Korea, China, Taiwan, and the East and West coasts of the United States. *Gloiopeltis* is harvested principally in southern Pacific coastal waters. The material is dried and ground or chopped for use in food.

(b) The ingredient meets the specifications for kelp in the Food Chemicals Codex, 3d Ed. (1981), p. 157, which is incorporated by reference, except that the loss on drying is not more than 20 percent and the maximum allowable level for iodine is 0.05 percent. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Spices, seasonings, and flavorings, § 170.3(n)(26) of this chapter	Not to exceed current good manufacturing practice	Flavor enhancer, § 170.3(o)(11) of this chapter, flavor adjuvant, § 170.3(o)(12) of this chapter

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 47376, Oct. 26, 1982]

§ 184.1133 Ammonium alginate.

(a) Ammonium alginate (CAS Reg. No. 9005-34-9) is the ammonium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Ammonium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 18, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Confections, frostings, § 170.3(n)(9) of this chapter	0.4	Stabilizer, thickener, § 170.3(o)(28) of this chapter
Fats and oils, § 170.3(n)(12) of this chapter	0.5	Do
Gelatins, puddings, § 170.3(n)(22) of this chapter	0.5	Do
Gravies and sauces, § 170.3(n)(24) of this chapter	0.4	Do
Jams and jellies, § 170.3(n)(28) of this chapter	0.4	Do.
Sweet sauces, § 170.3(n)(43) of this chapter	0.5	Do
All other food categories	0.1	Humectant, § 170.3(o)(16) of this chapter, stabilizer, thickener, § 170.3(o)(28) of this chapter

(d) Prior sanctions for ammonium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29950, July 9, 1982]

§ 184.1135 Ammonium bicarbonate.

(a) Ammonium bicarbonate (NH_4HCO_3, CAS Reg. No. 1066-33-7) is prepared by reacting gaseous carbon dioxide with aqueous ammonia. Crystals of ammonium bicarbonate are precipitated from solution and subsequently washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 19, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in

§ 170.3(o)(6) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; and a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52439, Nov. 18, 1983]

§ 184.1137 Ammonium carbonate.

(a) Ammonium carbonate ($(NH_4)_2CO_3$, CAS Reg. No. 8000-73-5) is a mixture of ammonium bicarbonate (NH_4HCO_3) and ammonium carbamate (NH_2COONH_4). It is prepared by the sublimation of a mixture of ammonium sulfate and calcium carbonate and occurs as a white powder or a hard, white or translucent mass.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 19, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in § 170.3(o)(17) of this chapter and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52439, Nov. 18, 1983]

§ 184.1138 Ammonium chloride.

(a) Ammonium chloride (NH_4Cl, CAS Reg. No. 12125-02-9) is produced by the reaction of sodium chloride and an ammonium salt in solution. The less soluble sodium salt separates out at elevated temperatures, and ammonium chloride is recovered from the filtrate on cooling. Alternatively, hydrogen chloride formed by the burning of hydrogen in chlorine is dissolved in water and then reacted with gaseous ammonia. Ammonium chloride is crystallized from the solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 20, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; and a processing aid as defined in § 107.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52439, Nov. 18, 1983]

§ 184.1139 Ammonium hydroxide.

(a) Ammonium hydroxide (NH_4OH, CAS Reg. No. 1336-21-6) is produced by passing ammonia gas into water.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 20, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in § 170.3(o)(17) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; a surface-finishing agent as defined in § 170.3(o)(30) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used as a boiler water good additive at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52440, Nov. 18, 1983]

§ 184.1141a Ammonium phosphate, monobasic.

(a) Ammonium phosphate, monobasic ($NH_4H_2PO_4$, CAS Reg. No. 7722-76-1) is manufactured by reacting ammonia with phosphoric acid at a pH below 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52440, Nov. 18, 1983]

§ 184.1141b Ammonium phosphate, dibasic.

(a) Ammonium phosphate, dibasic ($(NH_4)_2HPO_4$, CAS Reg. No. 7783-28-0) is manufactured by reacting ammonia with phosphoric acid at a pH above 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter; a firming agent as defined in § 170.3(o)(10) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52440. Nov. 18. 1983]

§ 184.1143 Ammonium sulfate.

(a) Ammonium sulfate ($(NH_4)_2SO_4$, CAS Reg. No. 7783-20-2) occurs naturally and consists of colorless or white, odorless crystals or granules. It is prepared by the neutralization of sulfuric acid with ammonium hydroxide.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp 22-23, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.15 percent for baked goods as defined in § 170.3(n)(1) of this chapter and 0.1 percent for gelatins and puddings as defined in § 170.1(n)(22) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086. Jan. 25. 1980; 45 FR 16469. Mar. 14. 1980. as amended at 49 FR 5611. Feb. 14. 1984]

§ 184.1155 Bentonite.

(a) Bentonite ($Al_2O_3 \cdot 4SiO_2 \cdot nH_2O$, CAS Reg. No. 1302-78-9) is principally a colloidal hydrated aluminum silicate. Bentonite contains varying quantities of iron, alkalies, and alkaline earths in the commercial products. Depending on the cations present, natural deposits of bentonite range in color from white to gray, yellow, green, or blue. Bentonite's fine particles provide large total surface area and, hence, pronounced adsorptive capability.

(b) FDA is developing food-grade specifications for bentonite in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a suitable purity for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice results in no significant residue in foods.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 43367. Oct. 1. 1982]

§ 184.1157 Benzoyl peroxide.

(a) Benzoyl peroxide ($(C_6H_5CO)_2O_2$, CAS Reg. No. 94-36-0) is a colorless, rhombic crystalline solid. It is prepared by reaction of benzoyl chloride, sodium hydroxide, and hydrogen peroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 35, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a bleaching agent in food.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: flour; milk used for production of Asiago fresh and Asiago soft cheese (§ 133.102), Asiago medium cheese (§ 133.103), Asiago old cheese (§ 133.104), Blue cheese (§ 133.106), Caciocavallo siciliano chesse (§ 133.111), Gorgonzola cheese (§ 133.141), Parmesan and reggiano cheese (§ 133.165), Provolone cheese (§ 133.181), Romano cheese (§ 133.183), and Swiss and emmentaler cheese (§ 133.195) in Part 133 of this chapter; and annatto-colored whey, such that the final bleached product conforms to the descriptions and specifications for whey, concentrated whey, or dried whey in § 184.1979(a) (1), (2), or (3), respectively.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 27173, July 30, 1986]

§ 184.1165 n-Butane and iso-butane.

(a) *n*-Butane and iso-butane (empirical formula C_4H_{10}, CAS Reg. Nos. 106-97-8 and 75-28-5, respectively) are colorless, odorless, flammable gases at normal temperatures and pressures. They are easily liquefied under pressure at room temperature and are stored and shipped in the liquid state. The butanes are obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The Food and Drug Administration is developing food-grade specifications for *n*-butane and iso-butane in cooperation with the National Academy of Sciences. In the interim, the ingredients must be of a purity suitable for their intended use.

(c) In accordance with § 184.1(b)(1), these ingredients are used in food with no limitations other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as propellants, aerating agents, and gases as defined in § 170.3(o)(25) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1185 Calcium acetate.

(a) Calcium acetate ($Ca(C_2H_3O_2)_2$, CAS Reg. No. 62-54-4), also known as acetate of lime or vinegar salts, is the calcium salt of acetic acid. It may be produced by the calcium hydroxide neutralization of acetic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 44, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a firming agent as defined in § 170.3(o)(10) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; processing aid as defined in § 170.3(o)(24) of this chapter; sequestrant as defined in § 170.3(o)(26) of this chapter; stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practices in accordance with § 184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 0.2 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.02 percent for cheese as defined in § 170.3(n)(5) of this chapter; 0.2 percent for gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; 0.15 percent for sweet sauces, toppings, and syrups as defined in § 170.3(n)(43) of this chapter; and 0.0001 percent for all other food categories.

( ) Prior sanctions for this ingredient different from the uses established in this section or in Part 181 of this chapter do not exist or have been waived.

[47 FR 27807, June 25, 1982]

§ 184.1187 Calcium alginate.

(a) Calcium alginate (CAS Reg. No. 9005-35-0) is the calcium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Calcium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents, or from sodium alginate by metathesis with appropriate calcium salts.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 45, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Baked goods, § 170.3(n)(1) of this chapter	0.002	Stabilizer, thickener, § 170.3(o)(28) of this chapter
Alcoholic beverages, § 170.3(n)(2) of this chapter	0.4	Do
Confections and frostings, § 170.3(n)(9) of this chapter	0.4	Do
Egg products, § 170.3(n)(11) of this chapter	0.6	Do
Fats and oils, § 170.3(n)(12) of this chapter	0.5	Do
Gelatins, puddings, § 170.3(n)(22) of this chapter	0.25	Do
Gravies and sauces, § 170.3(n)(24) of this chapter	0.4	Do
Jams and jellies, § 170.3(n)(28) of this chapter	0.5	Do
Sweet sauces, § 170.3(n)(43) of this chapter	0.5	Do
All other food categories	0.3	Do

(d) Prior sanctions for calcium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982]

§ 184.1191 Calcium carbonate.

(a) Calcium carbonate ($CaCO_3$, CAS Reg. No. 471-34-1) is prepared by three common methods of manufacture:

(1) As a byproduct in the "Lime soda process";

(2) By precipitation of calcium carbonate from calcium hydroxide in the "Carbonation process"; or

(3) By precipitation of calcium carbonate from calcium chloride in the "Calcium chloride process".

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 46, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from that set forth in Part 181 of this chapter, do not exist or have been waived.

[48 FR 52441, Nov. 18, 1983]

§ 184.1193 Calcium chloride.

(a) Calcium chloride ($CaCl_2 \cdot 2H_2O$, CAS Reg. No. 10035-04-8) or anhydrous calcium chloride ($CaCl_2$, CAS Reg. No. 10043-52-4) may be commercially obtained as a byproduct in the ammonia-soda (Solvay) process and as a joint product from natural salt brines, or it may be prepared by substitution reactions with other calcium and chloride salts.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 47, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an anticaking agent as defined in § 170.3(o)(1) of this chapter; antimicrobial agent as defined in § 170.3(o)(2) of this chapter; curing or pickling agent as defined in § 170.3(o)(5) of this chapter; firming agent as defined in § 170.3(o)(10) of this chapter; flavor enhancer as defined in § 170.3(o)(11) of this chapter; humectant as defined in § 170.3(o)(16) of this chapter; nutrient supplement as defined in § 170.3(o)(2) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; processing aid as defined in § 170.3(o)(24) of this chapter; stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; surface-active agent as defined in § 170.3(o)(29) of this chapter; synergist as defined in § 170.3(o)(31) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practices in accordance with § 184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 0.3 percent for baked goods as defined in § 170.3(n)(1) of this chapter and for dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.22 percent for nonalcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter; 0.2 percent for cheese as defined in § 170.3(n)(5) of this chapter and for processed fruit and fruit juices as defined in § 170.3(n)(35) of this chapter; 0.32 percent for coffee and tea as defined in § 170.3(n)(7) of this chapter; 0.4 percent for condiments and relishes as defined in § 170.3(n)(8) of this chapter; 0.2 percent for gravies and sauces as defined in § 170.3(n)(24) of this chapter; 0.1 percent for commercial jams and jellies as defined in § 170.3(n)(28) of this chapter; 0.25 percent for meat products as defined in § 170.3(n)(29) of this chapter; 2.0 percent for plant protein products as defined in § 170.3(n)(33) of this chapter; 0.4 percent for processed vegetables and vegetable juices as defined in § 170.3(n)(36) of this chapter; and 0.05 percent for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27808, June 25, 1982]

§ 184.1199 Calcium gluconate.

(a) Calcium gluconate ($[CH_2OH(CHOH)_4COO]_2Ca$, CAS Reg. No. 299-28-5) is the calcium salt of gluconic acid which may be produced by neutralization of gluconic acid with lime or calcium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 51, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a firming agent as defined in § 170.3(o)(10) of this chapter; formulation aid as defined in § 170.3(o)(14) of this chapter; sequestrant as defined in § 170.3(o)(26) of this chapter; stabilizer or thickener as defined in § 170.3(o)(28) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practices in accordance with § 184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 1.75 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.4 percent for dairy product analogs as defined in § 170.3(n)(10) of this chapter; 4.5 percent for gelatins and puddings as defined in § 170.3(n)(22) of this chapter; and 0.01 percent for sugar substitutes as defined in § 170.3(n)(42) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27808, June 25, 1982]

§ 184.1205 Calcium hydroxide.

(a) Calcium hydroxide ($Ca(OH)_2$, CAS Reg. No. 1305-62-0) is also known as slaked lime or calcium hydrate. It is produced by the hydration of lime.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 52, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 26714, June 29, 1984]

§ 184.1206 Calcium iodate.

(a) Calcium iodate [$Ca(IO_3)_2 \cdot H_2O$, CAS Reg. No. 7789-80-2], also referred to as lautarite, does not occur naturally but can be prepared by passing chlorine into a hot solution of lime ($CaCO_3$) in which iodine has been dissolved.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 53, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with § 184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1207 Calcium lactate.

(a) Calcium lactate ($C_6H_{10}CaO_6.xH_2O$, where x is any integer up to 5, CAS Reg. No. 814-80-2) is prepared commercially by the neutralization of lactic acid with calcium carbonate or calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 53, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a firming agent as defined in § 170.3(o)(10) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in § 170.3(o)(12) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in food, except in infant foods and infant formulas, at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 35367, Sept. 7, 1984]

§ 184.1210 Calcium oxide.

(a) Calcium oxide (CaO, CAS Reg. No. 1305-78-8) is also known as lime, quick lime, burnt lime, or calx. It is produced from calcium carbonate, limestone, or oyster shells by calcination at temperatures of 1,700-2,450° F.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 55, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 26714, June 29, 1984]

§ 184.1212 Calcium pantothenate.

(a) Calcium pantothenate ($(C_9H_{16}NO_5)_2Ca$, CAS Reg. No. of the *D*-isomer, 137-08-6) is a salt of pantothenic acid, one of the vitamins of the B complex. Only the *D*-isomer of pantothenic acid has vitamin activity, although both the *D*-isomer and the *DL*-racemic mixture of calcium pantothenate are used in food. Commercial calcium pantothenate is prepared synthetically from isobutyraldehyde and formaldehyde via 1,1-dimethyl-2-hydroxy-propionaldehyde and pantolactone.

(b) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. Calcium pantothenate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51908, Nov. 15, 1983]

§ 184.1221 Calcium propionate.

(a) Calcium propionate ($C_6H_{10}CaO_4$, CAS Reg. No. 4075-81-4) is the calcium salt of propionic acid. It occurs as white crystals or a crystalline solid, possessing not more than a faint odor of propionic acid. It is prepared by neutralizing propionic acid with calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 60, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; cheeses as defined in § 170.3(n)(5) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in

§ 170.3(n)(22) of this chapter; and jams and jellies as defined in § 170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13141, Apr. 3, 1984]

§ 184.1229 Calcium stearate.

(a) Calcium stearate ($Ca(C_{17}H_{35}COO)_2$, CAS Reg. No. 1529-23-0) is the calcium salt of stearic acid derived from edible sources. It is prepared as a white precipitate by mixing calcium chloride and sodium stearate in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 64, which is incorporated by reference, and the requirements of § 172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52445, Nov. 18, 1983]

§ 184.1230 Calcium sulfate.

(a) Calcium sulfate ($CaSO_4$, CAS Reg. No. 7778-18-9 or $CaSO_4 \cdot 2H_2O$, CAS Reg. No. 10101-41-4), also known as plaster of Paris, anhydrite, and gypsum, occurs naturally and exists as a fine, white to slightly yellow-white odorless powder. The anhydrous form is prepared by complete dehydration of gypsum, below 300° C. in an electric oven.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 66, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an anticaking agent as defined in § 170.3(o)(1) of this chapter, color and coloring adjunct as defined in § 170.3(o)(4) of this chapter, dough strengthener as defined in § 170.3(o)(6) of this chapter, drying agent as defined in § 170.3(o)(7) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flour treating agent as defined in § 170.3(o)(13) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, synergist as defined in § 170.3(o)(31) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 1.3 percent for baked goods as defined in § 170.3(n)(1) of this chapter, 3.0 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter, 0.5 percent for frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, 0.4 percent for gelatins and puddings as defined in § 170.3(n)(22) of this chapter, 0.5 percent for grain products and pastas as defined in § 170.3(n)(23) of this chapter, 0.35 percent for processed vegetables as defined in § 170.3(n)(36) of this chapter, and 0.07 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980; 45 FR 26319, Apr. 18, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1240 Carbon dioxide.

(a) Carbon dioxide (empirical formula CO_2, CAS Reg. No. 124-38-9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, dry ice, sublimes under atmospheric pressure at a temperature of −78.5° C. Carbon dioxide is prepared as a byproduct of the manufacture of lime during the "burning" of limestone, from the combustion of carbonaceous material, from fermentation processes, and from gases found in certain natural springs and wells.

(b) The Food and Drug Administration is developing food-grade specifications for carbon dioxide in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in § 170.3(o)(17) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1257 Clove and its derivatives.

(a) Cloves are the dried unopened flower buds and calyx tubes, harvested before the flowers have opened, of the clove tree *Eugenia caryophyllata* Thunberg, native to tropical Asia. Their derivatives include essential oils (cloves, CAS Reg. No. 8000-34-8; buds; leaves, CAS Reg. No. 8015-97-2; stems, CAS Reg. No. 8015-98-3; and eugenol, CAS Reg. No. 97-53-0), oleoresins, and natural extractives obtained from clove buds, leaves, and stems.

(b) Clove bud oil, clove leaf oil, clove stem oil, and eugenol meet the specifications of the "Food Chemicals Codex," (FCC), 3d Ed. (1981), pp. 87-89, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. As determined by analytical methods in FCC, clove oleorsin or other natural extractives (other than clove oils) meet FCC specifications for clove (clove bud) oil and the following modifications:

(1) The assay for phenols, as eugenol, by the FCC test, 3d Ed. (pp. 87-88), or the volatile oils content by the FCC test, 3d Ed. (pp. 87-88) should conform to the representation of the vendor;

(2) Optical rotation of the volatile oil between −2° and 0°;

(3) Refractive index of the volatile oil between 1.527 and 1.538 at 20° C;

(4) Specific gravity of the volatile oil between 1.036 and 1.060; and

(5) Residual solvent free, except those solvents that are GRAS or within tolerance levels as specified in Part 173, Subpart C, of this chapter.

(c) Clove and its derivatives are used as flavoring agents and adjuvants as defined in § 170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1).

(e) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[44 FR 3964, Jan 19, 1979, as amended at 47 FR 11852, Mar. 19, 1982; 49 FR 5611, Feb. 14, 1984]

§ 184.1259 Cocoa butter substitute primarily from palm oil.

(a) The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-stearin is "cocoa butter substitute primarily from palm oil." The ingredient is manufactured by directed esterification of fully saturated 1,3-diglycerides (derived from palm oil) with the anhydride of food-grade oleic acide in the presence of the catalyst trifluoromethane sulfonic acid (§ 173.395 of this chapter).

(b) The ingredient meets the following specifications:

(1) Over 90 percent triglycerides, not more than 7 percent diglycerides, not more than 1 percent monoglycerides, and not more than 1 percent free fatty acids.

(2) Total glycerides--98 percent minimum.

(3) Heavy metals (as lead), 10 parts per million maximum ("Food Chemicals Codex," 3d Ed. (1981), pp. 512-513, which is incorporated by reference, copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408).

(4) Color—clear, bright, and free from suspended matter.

(5) Odor and taste—free from foreign and rancid odor and taste.

(6) Residual catalyst ("Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 25.049-25.055, which is incorporated by reference), residual fluorine; limit of detection 0.2 part per million F; multiply fluoride result by 2.63 to convert to residual catalyst. Copies of the material incorporated by reference may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The ingredient shall be washed three times in batches with 0.5 percent sodium bicarbonate to remove catalyst residuals in accordance with good manufacturing practice.

(7) Residual methanol—5 parts per million maximum.

(c) In accordance with § 184.1(b)(1), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice: Confections and frostings as defined in § 170.3(n)(9) of this chapter; coatings of soft candy as defined in §170.3(n)(38) of this chapter; and sweet sauces and toppings as defined in §170.3(n)(43) of this chapter; except that the ingredient may not be used in a standardized food unless permitted by the standard of identity.

(d) The ingredient is used in food in accordance with § 184.1(b)(1) at levels not to exceed good manufacturing practice.

[43 FR 54239, Nov. 11, 1978, as amended at 47 FR 11852, Mar. 19, 1982; 49 FR 5611, Feb. 14, 1984; 49 FR 22799, June 1, 1984]

§ 184.1260 Copper gluconate.

(a) Copper gluconate (cupric gluconate $(CH_2OH(CHOH)_4COO)_2Cu$, CAS Reg. No. 527-09-3) is a substance that occurs as light blue to bluish-green, odorless crystals, or as a fine, light blue powder. It is prepared by the reaction of gluconic acid solutions with cupric oxide or basic cupric carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 90, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and as a synergist as defined in § 170.3(o)(31) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper gluconate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 24119, June 12, 1984]

§ 184.1261 Copper sulfate.

(a) Copper sulfate (cupric sulfate, $CuSO_4.5H_2O$, CAS Reg. No. 7758-98-7) usually is used in the pentahydrate form. This form occurs as large, deep blue or ultramarine, triclinic crystals; as blue granules, or as a light blue powder. The ingredient is prepared by the reaction of sulfuric acid with cupric oxide or with copper metal.

(b) FDA is developing food-grade specifications for copper sulfate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper sulfate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 24119, June 12, 1984]

§ 184.1262 Corn silk and corn silk extract.

(a) Corn silk is the fresh styles and stigmas of *Zea mays* L. collected when the corn is in milk. The filaments are extracted with dilute ethanol to produce corn silk extract. The extract may be concentrated at a temperature not exceeding 60°C.

(b) The Food and Drug Administration, in cooperation with the National Academy of Sciences, is developing food-grade specifications for corn silk and corn silk extract. In the interim, this ingredient must be of a suitable purity for its intended use.

(c) In accordance with § 184.1(b)(2), the ingredients are used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)[1]	Functional use
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	30	Flavoring agent, § 170.3(o)(12) of this chapter
Nonalcoholic beverages, § 170.3(n)(3) of this chapter	20	Do
Frozen dairy desserts, § 170.3(n)(20) of this chapter	10	Do
Soft candy, § 170.3(n)(38) of this chapter	20	Do
All other food categories	4	Do

[1] Parts per million.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29953, July 9, 1982]

§ 184.1265 Cuprous iodide.

(a) Cuprous iodide (copper (I) iodide, CuI, CAS Reg. No. 7681-65-4) is a pure white crystalline powder. It is prepared by the reaction of copper sulfate with potassium iodide under slightly acidic conditions.

(b) FDA is developing food-grade specifications for cuprous iodide in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Table salt	0.01 percent	Source of dietary iodine.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 24119, June 12, 1984]

§ 184.1271 L-Cysteine.

(a) L-Cysteine is the chemical L-2-amino-3-mercaptopropanoic acid ($C_3H_7O_2NS$).

(b) The ingredient meets the appropriate part of the specification set forth in the "Food Chemicals Codex," 3d Ed. (1981), pp. 92-93, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in § 170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1272 L-Cysteine monohydrochloride.

(a) L-Cysteine monohydrochloride is the chemical L-2-amino-3-mercaptopropanoic acid monohydrochloride monohydrate ($C_3H_7O_2NS\ HCl\ H_2O$).

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 92-93, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in § 170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1277 Dextrin.

(a) Dextrin ($((C_6H_{10}O_5)_n \cdot H_2O$, CAS Reg. No. 9004-53-9) is an incompletely hydrolyzed starch. It is prepared by dry heating corn, waxy maize, waxy milo, potato, arrowroot, wheat, rice, tapioca, or sago starches, or by dry heating the starches after: (1) Treatment with safe and suitable alkalis, acids, or pH control agents and (2) drying the acid or alkali treated starch.

(b) The ingredient meets the specification of the Food Chemicals Codex, 3d Ed. (1981), p. 96, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in

§ 170.3(o)(14) of this chapter; as a processing aid as defined in § 170.3(o)(24) of this chapter; as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; and as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51909, Nov. 15, 1983]

§ 184.1278 Diacetyl.

(a) Diacetyl ($C_4H_6O_2$, CAS Reg. No. 431-03-8) is a clear yellow to yellowish green liquid with a strong pungent odor. It is also known as 2,3-butanedione and is chemically synthesized from methyl ethyl ketone. It is miscible in water, glycerin, alcohol, and ether, and in very dilute water solution, it has a typical buttery odor and flavor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 368, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51907, Nov. 15, 1983]

§ 184.1282 Dill and its derivatives.

(a) Dill (American or European) is the herb and seeds from *Anethum graveolens* L., and dill (Indian) is the herb and seeds from *Anethum sowa*, D.C. Its derivatives include essential oils, oleoresins, and natural extractives obtained from these sources of dill.

(b) Dill oils meet the description and specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 100-102, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) Dill and its derivatives are used as flavoring agents and adjuvants as defined in § 170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) [Reserved]

(f) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1293 Ethyl alcohol.

(a) Ethyl alcohol (ethanol) is the chemical C_2H_5OH.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 112-113, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter on pizza crusts prior to final baking at levels not to exceed 2.0 percent by product weight.

(d) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1295 Ethyl formate.

(a) Ethyl formate ($C_3H_6O_2$, CAS Reg. No. 109-94-4) is also referred to as ethyl methanoate. It is an ester of formic acid and is prepared by esterification of formic acid with ethyl alcohol or by distillation of ethyl acetate and formic acid in the presence of concentrated sulfuric acid. Ethyl formate occurs naturally in some plant oils, fruits, and juices but does not occur naturally in the animal kingdom.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 376, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.05 percent in baked goods as defined in § 170.3(n)(1) of this chapter; 0.04 percent in chewing gum as defined in § 170.3(n)(6), hard candy as defined in § 170.3(n)(25), and soft candy as defined in § 170.3(n)(38) of this chapter; 0.02 percent in frozen dairy desserts as defined in § 170.3(n)(20) of this chapter; 0.03 percent in gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; and 0.01 percent in all other food categories.

(e) Prior sanctions for ethyl formate different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1317 Garlic and its derivatives.

(a) Garlic is the fresh or dehydrated bulb or cloves obtained from *Allium sativum*, a genus of the lily family. Its derivatives include essential oils, oleoresins, and natural extractives obtained from garlic.

(b) Garlic oil meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 132, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) Garlic and its derivatives are used as flavoring agents and adjuvants as defined in § 170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) [Reserved]

(f) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1318 Glucono delta-lactone.

(a) Glucono delta-lactone ($C_6H_{10}O_6$, CAS Reg. No. 90-80-2), also called *D*-gluconic acid delta-lactone or *D*-glucono-1,5-lactone, is the cyclic 1,5-intramolecular ester of *D*-gluconic acid. It is prepared by direct crystallization from the aqueous solution of gluconic acid. Gluconic acid may be produced by the oxidation of *D*-glucose with bromine water, by the oxidation of *D*-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals, or by the oxidation of *D*-glucose with enzymes derived from these microorganisms.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 134, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter leavening agent as defined in § 170.3(o)(17) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and sequestrant as defined in § 170.3(o)(26) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 33896, Sept. 24, 1986]

§ 184.1321 Corn gluten.

(a) Corn gluten (CAS Reg. No. 66071-96-3), also known as corn gluten meal, is the principal protein component of corn endosperm. It consists mainly of zein and glutelin. Corn gluten is a byproduct of the wet milling of corn for starch. The gluten fraction is washed to remove residual water soluble proteins. Corn gluten is also produced as a byproduct during the conversion of the starch in whole or various fractions of dry milled corn to corn syrups.

(b) FDA is developing food-grade specifications for corn gluten in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8998, Mar. 6, 1985]

§ 184.1322 Wheat gluten.

(a) Wheat gluten (CAS Reg. No. 8002-80-0) is the principal protein component of wheat and consists mainly of gliadin and glutenin. Wheat gluten is obtained by hydrating wheat flour and mechanically working the sticky mass to separate the wheat gluten from the starch and other flour components. Vital gluten is dried gluten that has retained its elastic properties.

(b) FDA is developing food-grade specifications for wheat gluten in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; a surface-finishing agent as defined in § 170.3(o)(30) of this chapter; and a texturizing agent as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8998, Mar. 6, 1985]

§ 184.1330 Acacia (gum arabic).

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 7, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages and beverage bases, § 170.3(n)(3) of this chapter	2.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Chewing gum, § 170.3(n)(6) of this chapter	5.6	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; humectant, § 170.3(o)(16) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Confections and frostings, § 170.3(n)(9) of this chapter	12.4	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Dairy product analogs, § 170.3(n)(10) of this chapter	1.3	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Fats and oils, § 170.3(n)(12) of this chapter	1.5	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter	2.5	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Hard candy and cough drops, § 170.3(n)(25) of this chapter	46.5	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.
Nuts and nut products, § 170.3(n)(32) of this chapter	8.3	Formulation aid, § 170.3(o)(14) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Snack foods, § 170.3(n)(37) of this chapter	4.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.
Soft candy, § 170.3(n)(38) of this chapter	85.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; humectant, § 170.3(o)(16) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
All other food categories	1.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; processing aid, § 170.3(o)(24) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter; texturizer, § 170.3(o)(32) of this chapter.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1983]

§ 184.1333 Gum ghatti.

(a) Gum ghatti (Indian gum) is an exudate from wounds in the bark of *Anogeissus latifolia*, a large tree found in the dry deciduous forests of India and Ceylon.

(b) The ingredient complies with the following specifications:

(1) *Viscosity of a 1-percent solution.* Not less than the minimum or within the range claimed by the vendor.

(2) *Limits of impurities*—(i) *Arsenic (as AL).* Not more than 3 parts per million (0.0003 percent);

(ii) *Ash (acid-insoluble).* Not more than 1.75 percent;

(iii) *Ash (total).* Not more than 6.0 percent;

(iv) *Heavy metals (as Pb).* Not more than 40 parts per million (0.004 percent); and

(v) *Lead.* Not more than 10 parts per million (0.001 percent).

(3) *Loss on drying.* Not more than 14 percent dried at 105° C for 5 hours.

(4) *Identification test.* Add 0.2 ml of diluted lead acetate as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 31.178(b), p. 529, under "Dilute Basic Lead Acetate Standard Solution," which is incorporated by reference (copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), to 5 ml of a cold 1-in-100 aqueous solution of the gum. An immediate, voluminous, opaque precipitate indicates acacia. A small precipitate or clear solution which produces an opaque flocculent precipitate upon the additon of 1 ml of 3 *N* ammonimum hydroxide indicates gum ghatti.

(c) The ingredient is used in food under the following conditions:

Maximum Usage Levels Permitted

Food (as served)	Percent	Function
Beverages and beverage bases, nonalcoholic, § 170.3(n)(3) of this chapter	0.2	Emulsifier and emulsifier salt § 170.3(o)(8) of this chapter
All other food categories	1	Emulsifier and emulsifier salt § 170.3(o)(8) of this chapter

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1339 Guar gum.

(a) Guar gum is the natural substance obtained from the maceration of the seed of the guar plant, *Cyamopsis tetragonoloba* (Linne) Taub., or *Cyamopsis psoraloides* (Lam.) D.C.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 141, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.35	Emulsifier and emulsifier salts, § 170.3(o)(8) of this chapter, formulation aid, § 170.3(o)(14) of this chapter, stabilizer and thickener, § 170.3(o)(28) of this chapter
Breakfast cereals, § 170.3(n)(4) of this chapter	1.2	Formulation aid, § 170.3(o)(14) of this chapter, stabilizer and thickener, § 170.3(o)(28) of this chapter
Cheese, § 170.3(n)(5) of this chapter	.8	Do
Dairy products analogs, § 170.3(n)(10) of this chapter	1.0	Firming agent, § 170.3(o)(10) of this chapter, formulation aid, § 170.3(o)(14) of this chapter, stabilizer and thickener, § 170.3(o)(28) of this chapter
Fats and oils, § 170.3(n)(12) of this chapter	2.0	Do
Gravies and sauces, § 170.3(n)(24) of this chapter	1.2	Formulation aid, § 170.3(o)(14) of this chapter, stabilizer and thickener, § 170.3(o)(28) of this chapter
Jams and jellies, commercial, § 170.3(n)(28) of this chapter	1.0	Do
Milk products, § 170.3(n)(31) of this chapter	.6	Do
Processed vegetables and vegetable juices, § 170.3(n)(36) of this chapter	2.0	Formulation aid, § 170.3(o)(14) of this chapter, stabilizer and thickener, § 170.3(o)(28) of this chapter

MAXIMUM USAGE LEVELS PERMITTED—Continued

Food (as served)	Percent	Function
Soups and soup mixes, § 170.3(n)(40) of this chapter	8	Do
Sweet sauces, toppings and syrups, § 170.3(n)(43) of this chapter	1.0	Do
All other food categories	5	Emulsifier and emulsifier salts, § 170.3(o)(8) of this chapter, firming agent, § 170.3(o)(10) of this chapter, formulation aid, § 170.3(o)(14) of this chapter, stabilizer and thickener, § 170.3(o)(28) of this chapter

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1343 Locust (carob) bean gum.

(a) Locust (carob) bean gum is primarily the macerated endosperm of the seed of the locust (carob) bean tree, *Ceratonia siliqua* (Linne), a leguminous evergreen tree, with lesser quantities of seed coat and germ.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 174-175, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used at levels not to exceed the following maximum levels:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.15	Stabilizer and thickener, § 170.3(o)(28) of this chapter
Beverages and beverage bases, nonalcoholic, § 170.3(n)(3) of this chapter	25	Do
Cheeses, § 170.3(n)(5) of this chapter	8	Do
Gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter	75	Do
Jams and jellies, commercial, § 170.3(n)(28) of this chapter	75	Do
All other food categories	5	Do

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1349 Karaya gum (sterculia gum).

(a) Karaya gum (sterculia gum) is the dried gummy exudate from the trunk of trees of various species of the genus *Sterculia*.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 157, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Frozen dairy desserts and mixes, § 170.3(n)(20) of this chapter	0.3	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter
Milk products, § 170.3(n)(31) of this chapter	02	Stabilizer and thickener, § 170.3(o)(28) of this chapter
Soft candy, § 170.3(n)(38) of this chapter	9	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter
All other food categories	002	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1351 Gum tragacanth.

(a) Gum tragacanth is the exudate from one of several species of *Astragalus gummifier* Labillardiere, a shrub that grows wild in mountainous regions of the Middle East.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 337, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter
Condiments and relishes, § 170.3(n)(8) of this chapter	7	Do
Fats and oils, § 170.3(n)(12) of this chapter	1.3	Do
Gravies and sauces, § 170.3(n)(24) of this chapter	8	Do
Meat products, § 170.3(n)(29) of this chapter	2	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter	2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter
All other food categories	1	Do

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1355 Helium.

(a) Helium (empirical formula He, CAS Reg. No. 7440-59-7) is a colorless, odorless, flavorless, nonflammable, inert gas. It is lighter than air and is produced by the liquefaction and purification of natural gas.

(b) The Food and Drug Administration is developing food-grade specifications for helium in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1366 Hydrogen peroxide.

(a) Hydrogen peroxide (H_2O_2, CAS Reg. No. 7722-84-1) is also referred to as hydrogen dioxide. It is made by the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt with subsequent hydrolysis and distillation of the hydrogen peroxide formed; by decomposition of barium peroxide with sulfuric or phosphoric acid; by hydrogen reduction of 2-ethylanthraquinone, followed by oxidation with air, to regenerate the quinone and produce hydrogen peroxide; or by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 146-147,[1] which is incorporated by reference.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under Part 133 of this chapter	0.05	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods.	0.04	do.
Dried eggs, dried egg whites, and dried egg yolks as in §§ 160.105, 160.145, and 160.185 of this chapter	Amount sufficient for the purpose	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
Tripe	do	Bleaching agent.
Beef feet	Amount sufficient for the purpose (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide)	Bleaching agent.
Herring	Amount sufficient for the purpose	do.
Wine	do	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
Starch	0.15	Antimicrobial agent as defined in §170.3 (o)(2) of this chapter, to produce thermophile-free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea	Amount sufficient for the purpose	Bleaching agent.
Corn syrup	0.15	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey	0.05	Bleaching agent.
Wine vinegar	Amount sufficient for the purpose	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.
Emulsifiers containing fatty acid esters	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

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[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[46 FR 44439, Sept. 4, 1981, as amended at 51 FR 27172, July 30, 1986]

§ 184.1370 Inositol.

(a) Inositol, or myo-inositol ($C_6H_{12}O_6$, CAS Reg. No. 87-89-8), is *cis*-1,2,3,5-*trans*-4,6-cyclohexanehexol. It occurs naturally and is prepared from an aqueous (0.2 percent sulfur dioxide) extract of corn kernels by precipitation and hydrolysis of crude phytate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 150, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in special dietary foods as defined in Part 105 of this chapter at levels not to exceed current good manufacturing practice. It may also be used in infant formula in accordance with section 412(g) of the Act, or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established by this section do not exist or have been waived.

[47 FR 38278, Aug. 31, 1982]

§ 184.1372 Insoluble glucose isomerase enzyme preparations.

(a) Insoluble glucose isomerase enzyme preparations are used in the production of high fructose corn syrup described in § 182.1866 of this chapter. They are derived from recognized species of precisely classified, nonpathogenic, and nontoxicogenic microorganisms, including *Streptomyces rubiginosus*, *Actinoplanes missouriensis*, *Streptomyces olivaceus*, *Streptomyces olivochromogenes*, and *Bacillus coagulans*, that have been grown in a pure culture fermentation that produces no antibiotics. They are fixed (rendered insoluble) for batch production with GRAS ingredients or may be fixed for further immobilization with either GRAS ingredients or materials approved under § 173.357 of this chapter.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, to convert glucose to fructose.

(2) The ingredient is used in high fructose corn syrup, at levels not to exceed current good manufacturing practice.

[48 FR 5720, Feb. 8, 1983]

§ 184.1388 Lactase enzyme preparation from Kluyveromyces lactis.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic yeast *Kluyveromyces lactis* (previously named *Saccharomyces lactis*). It contains the enzyme β-galactoside galactohydrase (CAS Reg. No. CBS 683), which converts lactose to glucose and galactose. It is prepared from yeast that has been grown in a pure culture fermentation and by using materials that are generally recognized as safe or are food additives that have been approved for this use by the Food and Drug Administration.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107-110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to convert lactose to glucose and galactose.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is to use this ingredient in milk to produce lactase-treated milk, which contains less lactose than regular milk, or lactose-reduced milk, which contains at least 70 percent less lactose than regular milk.

[49 FR 47387, Dec. 4, 1984]

§ 184.1400 Lecithin.

(a) Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils. Lecithin is bleached, if desired, by hydrogen peroxide and benzoyl peroxide and dried by heating.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 166-167, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51150, Nov. 7, 1983]

§ 184.1408 Licorice and licorice derivatives.

(a) (1) Licorice (glycyrrhiza) root is the dried and ground rhizome and root portions of *Glycyrrhiza glabra* or other species of *Glycyrrhiza*. Licorice extract is that portion of the licorice root that is, after maceration, extracted by boiling water. The extract can be further purified by filtration and by treatment with acids and ethyl alcohol. Licorice extract is sold as a liquid, paste ("block"), or spray-dried powder.

(2) Ammoniated glycyrrhizin is prepared from the water extract of licorice root by acid precipitation followed by neutralization with dilute ammonia. Monoammonium glycyrrhizinate ($C_{42}H_{61}O_{16}NH_45H_2O$, CAS Reg. No. 1407-03-0) is prepared from ammoniated glycyrrhizin by solvent extraction and separation techniques.

(b) The ingredients shall meet the following specifications when analyzed:

(1) *Assay.* The glycyrrhizin content of each flavoring ingredient shall be determined by the method in the Official Methods of Analysis of the Association of Official Analytical Chemists, 13th Ed., §§ 19.136-19.140, which is incorporated by reference, or by methods 19.CO1 through 19.CO4 in the *Journal of the Association of Official Analytical Chemists*, 65:471-472 (1982), which are also incorporated by reference. Copies of all of these methods are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Ash.* Not more than 9.5 percent for licorice, 2.5 percent for ammoniated glycyrrhizin, and 0.5 percent for monoammonium glycyrrhizinate on an anhydrous basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 466, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) *Acid unsoluble ash.* Not more than 2.5 percent for licorice on an anhydrous basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p 466, which is incorporated by reference.

(4) *Heavy metals (as Pb).* Not more than 40 parts per million as determined by method II in the Food Chemicals Codex, 3d Ed. (1981), p. 512, which is incorporated by reference.

(5) *Arsenic (As).* Not more than 3 parts per million as determined by the method in the Food Chemicals Codex. 3d Ed. (1981), p. 464, which is incorporated by reference.

(c) In accordance with § 184.1(b)(2), these ingredients are used in food only within the following specific limitations:

Category of food	Maximum level in food (percent glycyrrhizin content of food) (as served)	Functional use
Baked foods, §170.3(n)(1) of this chapter	0.05	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(o)(12) of this chapter
Alcoholic beverages, §170.3(n)(2) of this chapter	0.1	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(o)(12) of this chapter; surface-active agent, §170.3(o)(29) of this chapter.
Nonalcoholic beverages, §170.3(n)(3) of this chapter	0.15	Do.
Chewing gum, §170.3(n)(6) of this chapter	1.1	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent, §170.3(n)(12) of this chapter.
Hard candy, §170.3(n)(25) of this chapter	16.0	Do.
Herbs and seasonings, §170.3(n)(26) of this chapter	0.15	Do.
Plant protein products, §170.3(n)(33) of this chapter	0.15	Do.
Soft candy, §170.3(n)(38) of this chapter	3.1	Do.
Vitamin or mineral dietary supplements	0.5	Do.
All other foods except sugar substitutes, §170.3(n)(42) of this chapter. The ingredient is not permitted to be used as a nonnutritive sweetener in sugar substitutes	0.1	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 21044, May 22, 1985]

§ 184.1409 Ground limestone.

(a) Ground limestone consists essentially (not less than 94 percent) of calcium carbonate ($CaCO_3$) and is prepared by the crushing, grinding, and classifying of naturally occurring limestone.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 173, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1425 Magnesium carbonate.

(a) Magnesium carbonate (molecular formula approximately $(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$, CAS Reg. No. 39409-82-0) is also known as magnesium carbonate hydroxide. It is a white powder formed either by adding an alkaline carbonate (such as sodium carbonate) to a solution of magnesium sulfate or by carbonation of a slurry of magnesium hydroxide followed by boiling of the resulting magnesium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking and free-flow agent as defined in § 170.3(o)(1) of this chapter; a flour treating agent as defined in § 170.3(o)(13) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a synergist as defined in § 170.3(o)(31) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13558, Apr. 5, 1985; 50 FR 16080, Apr. 24, 1985]

§ 184.1426 Magnesium chloride.

(a) Magnesium chloride ($MgCl_2.6H_2O$, CAS Reg. No. 7786-30-3) is a colorless, deliquescent, crystalline material that occurs naturally as the mineral bischofite. It is prepared by dissolving magnesium oxide, hydroxide, or carbonate in aqueous hydrochloric acid solution and crystallizing out magnesium chloride hexahydrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985; 50 FR 16080, Apr. 24, 1985]

§ 184.1428 Magnesium hydroxide.

(a) Magnesium hydroxide ($Mg(OH)_2$, CAS Reg. No. 1409-42-8) occurs naturally as the colorless, crystalline mineral brucite. It is prepared as a white precipitate by the addition of sodium hydroxide to a water soluble magnesium salt or by hydration of reactive grades of magnesium oxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 178, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985]

§ 184.1431 Magnesium oxide.

(a) Magnesium oxide (MgO, CAS Reg. No. 1309-48-4) occurs naturally as the colorless, crystalline mineral periclase. It is produced either as a bulky white powder (light) or a relatively dense white powder (heavy) by heating magnesium hydroxide or carbonate. Heating these magnesium salts under moderate conditions (400° to 900° C for a few hours) produces light magnesium oxide. Heating the salts under more rigorous conditions (1200° C for 12 hours) produces heavy magnesium oxide. Light magnesium oxide is converted to heavy magnesium oxide by sustained heating at high temperatures.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 178, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking and free-flow agent as defined in § 170.3(o)(1) of this chapter; a firming agent as defined in § 170.3(o)(10) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not be exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985]

§ 184.1434 Magnesium phosphate.

(a) Magnesium phosphate includes both magnesium phosphate, dibasic, and magnesium phosphate, tribasic. Magnesium phosphate, dibasic ($MgHPO_4 \cdot 3H_2O$, CAS Reg. No. 7782-75-4) occurs naturally as the white, crystalline mineral newberyite. It is prepared commercially as a precipitate formed by treating a solution of magnesium sulfate with disodium phosphate under controlled conditions. Magnesium phosphate, tribasic ($Mg_3(PO_4)_2 \cdot xH_2O$, CAS Reg. No. 7727-87-1) may contain 4, 5, or 8 molecules of water of hydration. It is produced as a precipitate from a solution of magnesite with phosphoric acid.

(b) Magnesium phosphate, dibasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 179, which is incorporated by reference. Magnesium phosphate, tribasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 180, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L Street, NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1440 Magnesium stearate.

(a) Magnesium stearate ($Mg(C_{17}H_{34}COO)_2$, CAS Reg. No. 557-04-0) is the magnesium salt of stearic acid. It is produced as a white precipitate by the addition of an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate derived from stearic acid that is obtained from edible sources and that conforms to the requirements of § 172.860(b)(2) of this chapter.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 182, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1443 Magnesium sulfate.

(a) Magnesium sulfate ($MgSO_4 \cdot 7H_2O$, CAS Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 183, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1444 Maltodextrin.

(a) Maltodextrin ($(C_6H_{10}O_5)_n$, CAS Reg. No. 9050-36-6) is a nonsweet nutritive saccharide polymer that consists of D-glucose units linked primarily by α-1-4 bonds and that has a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch with safe and suitable acids and enzymes.

(b) FDA is developing food-grade specifications for maltodextrin in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51911, Nov. 15, 1983]

§ 184.1445 Malt syrup (malt extract).

(a) Malt is the product of barley (*Hordeum vulgare* L.) germinated under controlled conditions. Malt syrup and malt extract are interchangeable terms for a viscous concentrate of water extract of germinated barley grain, with or without added safe preservative. Malt syrup is usually a brown, sweet, and viscous liquid containing varying amounts of amylolytic enzymes and plant constituents. Barley is first softened after cleaning by steeping operations and then allowed to germinate under controlled conditions. The germinated grain then undergoes processing, such as drying, grinding, extracting, filtering, and evaporating, to produce malt syrup (malt extract) with 75 to 80 percent solids or dried malt syrup with higher solids content.

(b) FDA is developing food-grade specifications for malt syrup (malt extract) in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51613, Nov. 10, 1983]

§ 184.1446 Manganese chloride.

(a) Manganese chloride ($MnCl_2.4H_2O$, CAS Reg. No. 7773-01-5) is a pink, translucent, crystalline product. It is also known as manganese dichloride. It is prepared by dissolving manganous oxide, pyrolusite ore (MnO_2), or reduced manganese ore in hydrochloric acid. The resulting solution is neutralized to precipitate heavy metals, filtered, concentrated, and crystallized.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19165, May 7, 1985]

§ 184.1449 Manganese citrate.

(a) Manganese citrate ($Mn_3(C_6H_5O_7)_2$, CAS Reg. No. 1002-46-65) is a pale orange or pinkish white powder. It is obtained by precipitating manganese carbonate from manganese sulfate and sodium carbonate solutions. The filtered [illegible] washed precipitate is digested first with sufficient citric acid solution to form manganous citrate and then with sodium citrate to complete the reaction.

(b) FDA is developing food-grade specifications for manganese citrate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; fish products as defined in § 170.3(n)(13) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; and poultry products as defined in § 170.3(n)(34) of this chapter. The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19166, May 7, 1985]

§ 184.1452 Manganese gluconate.

(a) Manganese gluconate ($C_{12}H_{22}MnO_{14}\cdot 2H_2O$, CAS Reg. No. 648-53-98) is a slightly pink colored powder. It is obtained by reacting manganese carbonate with gluconic acid in aqueous medium and then crystallizing the product.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; fish products as defined in § 170.3(n)(13) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; and poultry products as defined in § 170.3(n)(34) of this chapter. The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cos-

metic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19166, May 7, 1985]

§ 184.1461 Manganese sulfate.

(a) Manganese sulfate ($MnSO_4 \cdot H_2O$, CAS Reg. No. 7785-87-7) is a pale pink, granular, odorless powder. It is obtained by reacting manganese compounds with sulfuric acid. It is also obtained as a byproduct in the manufacture of hydroquinone. Other manufacturing processes include the action of sulfur dioxide on a slurry of manganese dioxide in sulfuric acid, and the roasting of pyrolusite (MnO_2) ore with solid ferrous sulfate and coal, followed by leaching and crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 188, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; fish products as defined in § 170.3(n(13) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; and poultry products as defined in § 170.3(n)(34) of this chapter.

The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19166, May 7, 1985]

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl *p*-hydroxybenzoate. It is produced by the methanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1530 Niacin.

(a) Niacin ($C_6H_5NO_2$, CAS Reg. No. 59-67-6) is the chemical 3-pyridinecarboxylic acid (nicotinic acid). It is a non-hygroscopic, stable, white, crystalline solid that sublimes without decomposition at about 230° C. It is soluble in water and alcohol. It is insoluble in ether.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 205, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983]

§ 184.1535 Niacinamide.

(a) Niacinamide ($C_6H_6N_2O$, CAS Reg. No. 98-92-0) is the chemical 3-pyridinecarboxylic acid amide (nicotinamide). It is a white crystalline powder that is soluble in water, alcohol, ether, and glycerol. It melts between 128° and 131° C.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 205, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983]

§ 184.1537 Nickel.

(a) Elemental nickel (CAS Reg. No. 7440-02-0) is obtained from nickel ore by transforming it to nickel sulfide (Ni_3S_2). The sulfide is roasted in air to give nickel oxide (NiO). The oxide is then reduced with carbon to give elemental nickel.

(b) The Food and Drug Administration is developing food-grade specifications for nickel in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a catalyst as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the hydrogenation of fats and oils as defined in § 170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice. Current good manufacturing practice includes the removal of nickel from fats and oils following hydrogenation.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51618, Nov. 10, 1983]

§ 184.1540 Nitrogen.

(a) Nitrogen (empirical formula N_2, CAS Reg. No. 7727-37-9) is a colorless, odorless, flavorless gas that is produced commercially by the fractionation of liquid air.

(b) The Food and Drug Administration is developing food-grade specifications for nitrogen in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1545 Nitrous oxide.

(a) Nitrous oxide (empirical formula N_2O, CAS Reg. No. 10024-97-2) is also known as dinitrogen monoxide or laughing gas. It is a colorless gas, about 50 percent heavier than air, with a slightly sweet smell. It does not burn but will support combustion. Nitrous oxide is manufactured by the thermal decomposition of ammonium nitrate. Higher oxides of nitrogen are removed by passing the dry gas through a series of scrubbing towers.

(b) The Food and Drug Administration is developing food-grade specifications for nitrous oxide in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in dairy product analogs as defined in § 170.3(n)(10) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1553 Peptones.

(a) Peptones are a variable mixture of polypeptides, oligopeptides, and amino acids that are produced by partial hydrolysis of casein, animal tissue, soy protein isolate, gelatin, defatted fatty tissue, egg albumin, or lactalbumin (whey protein). Peptones are produced from these proteins using proteolytic enzymes that either are considered to be generally recognized as safe (GRAS) or are regulated as food additives. Peptones are also produced by denaturing any of the proteins listed in this paragraph with safe and suitable acids or heat.

(b) FDA is developing food-grade specifications for peptones in cooperation with the National Academy of Sciences. In the interim, these ingredients must be of a purity suitable for their intended use.

(c) In accordance with § 184.1(b)(1), these ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as GRAS as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) These ingredients are used as nutrient supplements as defined in § 170.3(o)(20) of this chapter; as proc-

essing aids as defined in § 170.3(o)(24) of this chapter; and as surface-active agents as defined in § 170.3(o)(29) of this chapter.

(2) These ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[49 FR 25430, June 21, 1984, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1555 Rapeseed oil.

(a) *Fully hydrogenated rapeseed oil.* (1) Fully hydrogenated rapeseed oil is a mixture of triglycerides in which the fatty acid composition is a mixture of saturated fatty acids. The fatty acids are present in the same porportions which result from the full hydrogenation of fatty acids occurring in natural rapeseed oil. The rapeseed oil is obtained from the *napus* and *campestris* varieties of *Brassica* of the family Cruciferae. It is prepared by fully hydrogenating refined and bleached rapeseed oil at 310-375° F, using a catalyst such as nickel, until the iodine number is 4 or less.

(2) The ingredient meets the following specifications: Acid value not more than 6, arsenic not more than 3 parts per million, free glycerin not more than 7 percent, heavy metals (as Pb) not more than 10 parts per million, iodine number not more than 4, residue on ignition not more than 0.5 percent.

(3) The ingredient is used as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter in peanut butter. The use level of the ingredient is limited by good manufacturing practice (GMP) to the minimum amount required to produce the intended effect. Current good manufacturing practices result in a maximum level of 2 percent in peanut butter.

(b) *Superglycerinated fully hydrogenated rapeseed oil.* (1) Superglycerinated fully hydrogenated rapeseed oil is a mixture of mono- and diglycerides with triglycerides as a minor component. The fatty acid composition is a mixture of saturated fatty acids present in the same proportions as those resulting from the full hydrogenation of fatty acids in natural rapeseed oil. It is made by adding excess glycerol to the fully hydrogenated rapeseed oil and heating, in the presence of a sodium hydroxide catalyst, to 330° F under partial vacuum and steam sparging agitation.

(2) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 201, relating to mono- and diglycerides, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. An additional specification requires the iodine number to be 4 or less.

(3) The ingredient is used as an emulsifier as defined in § 170.3(o)(8) of this chapter in shortenings for cake mixes. The use level of the ingredient is limited by good manufacturing practice (GMP) to the minimum amount required to produce the intended effect. Current good manufacturing practices result in a maximum level, as served, of 4 percent of the shortening or 0.5 percent of the total weight of the cake mix.

(c) *Low erucic acid rapeseed oil.* (1) Low erucic acid rapeseed oil is the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica napus* or *B. campestris* of the family *Cruciferae*. The plant varieties are those producing oil-bearing seeds with a low erucic acid content. Chemically, low erucic acid rapeseed oil is a mixture of triglycerides, composed of both saturated and unsaturated fatty acids, with an erucic acid content of no more than 2 percent of the component fatty acids.

(2) Low erucic acid rapeseed oil as defined in paragraph (c)(1) of this section may be partially hydrogenated to reduce the proportion of unsaturated fatty acids. When the partially hydrogenated low erucic acid rapeseed oil is used, it shall be referred to as partially hydrogenated low erucic acid rapeseed oil.

(3) In addition to limiting the content of erucic acid to a level not exceeding 2 percent of the component fatty acids, FDA is developing other

food-grade specifications for low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil in cooperation with the National Academy of Sciences. In the interim, the ingredients must be of a purity suitable for their intended use.

(4) Low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil are used as edible fats and oils in food, except in infant formula, at levels not to exceed current good manufacturing practice.

[42 FR 48336, Sept. 23, 1977, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 3755, Jan. 28, 1985]

§ 184.1560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008-63-7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.[1]

(c) The ingredient is used as a surfactant as defined in § 170.3 (o)(29) of this chapter.

(d) The ingredient is used in food in accordance with § 184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in § 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 36064, Aug. 15, 1978. Redesignated and amended at 50 FR 49537, Dec. 3, 1985]

§ 184.1563 Ozone.

(a) Ozone (O_3, CAS Reg. No. 10028-15-6) is an unstable blue gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 103.35 (b) through (e) of this chapter	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water	Antimicrobial agent, § 170.3 (o)(2) of this chapter

[47 FR 50210, Nov. 5, 1982]

§ 184.1585 Papain.

(a) Papain (CAS Reg. No. 9001-73-4) is a proteolytic enzyme derived from *Carica papaya* L. Crude latex containing the enzyme is collected from slashed unripe papaya. The food-grade product is obtained by repeated filtration of the crude latex or an aqueous solution of latex or by precipitation from an aqueous solution of latex. The resulting enzyme preparation may be used in a liquid or dry form.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 107-110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than currect good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing conditions of use:

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[1] Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter; processing aid as defined in § 170.3(o)(24) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 48806, Oct. 21, 1983]

§ 184.1588 Pectins.

(a) The pectins (CAS Reg. No. 9000-69-5) are a group of complex, high molecular weight polysaccharides found in plants and composed chiefly of partially methylated polygalacturonic acid units. Portions of the carboxly group occur as methyl esters, and the remaining carboxyl groups exist in the form of the free acid or as its ammonium, potassium, or sodium (CAS Reg. No. 9000-59-8) salts, and in some types as the acid amide. Thus, the pectins regulated in this section are the high-ester pectins, low-ester pectins, amidated pectins, pectinic acids, and pectinates. Pectin is produced commercially by extracting citrus peel, apple pomace, or beet pulp with hot dilute acid (pH 1.0 to 3.5, 70° to 90° C). The extract is filtered, and pectin is then precipitated from the clear extract with ethanol or isopropanol, or as the copper or aluminum salt. The acid extract is sometimes spray- or roller-dried, or it is concentrated to be sold as liquid pectin.

(b) The ingredients meet the specifications of the Food Chemical Codex, 3d Ed. (1981), p. 215, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as emulsifiers as defined in § 170.3(o)(8) of this chapter and as stabilizers and thickeners as defined in § 170.3(o)(28) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[48 FR 51149, Nov. 7, 1983]

§ 184.1610 Potassium alginate.

(a) Potassium alginate (CAS Reg. No. 9005-36-1) is the potassium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Potassium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Confections and frostings, § 170.3(n)(9) of this chapter	0.1	Stabilizer, thickener, § 170.3(o)(28) of this chapter
Gelatins and puddings § 170.3(n)(22) of this chapter	0.7	Do

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Processed fruits and fruit juices § 170.3(n)(35) of this chapter	0.25	Do
All other food categories	0.01	Do

(d) Prior sanctions for potassium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982]

§ 184.1613 Potassium bicarbonate.

(a) Potassium bicarbonate ($KHCO_3$, CAS Reg. No. 298-14-6) is made by the following processes:

(1) By treating a solution of potassium hydroxide with carbon dioxide;

(2) By treating a solution of potassium carbonate with carbon dioxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter; nutrient supplemlent as defined in § 170.3(o)(20) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1619 Potassium carbonate.

(a) Potassium carbonate (K_2CO_3, CAS Reg. No. 584-08-7) is produced by the following methods of manufacture:

(1) By electrolysis of potassium chloride followed by exposing the resultant potassium to carbon dioxide;

(2) By treating a solution of potassium hydroxide with excess carbon dioxide to produce potassium carbonate;

(3) By treating a solution of potassium hydroxide with carbon dioxide to produce potassium bicarbonate, which is then heated to yield potassium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 240, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. the affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; nutrient supplement as defined in § 170.3(o)(20) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1622 Potassium chloride.

(a) Potassium chloride (KCl, CAS Reg. No. 7447-40-7) is a white, odorless solid prepared from source minerals by fractional crystallization or flotation. It is soluble in water and glycerol and has a saline taste at low concentration levels.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 241, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter; as a flavoring agent as defined in § 170.3(o)(12) of this chapter; as a nutrient supplement as defined in § 170.3(o)(20) of this chapter; as a pH control agent as defined in §170.3(o)(23) of this chapter; and as a stabilizer or thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Potassium chloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51614, Nov. 10, 1983]

§ 184.1631 Potassium hydroxide.

(a) Potassium hydroxide (KOH, CAS Reg. No. 1310-58-3) is also known as caustic potash, potash lye, and potassa. The empirical formula is KOH. It is a white, highly deliquescent caustic solid, which is marketed in several forms, including pellets, flakes, sticks, lumps, and powders. Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available from inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter; a pH control agent as defined in § 170.3(o)(23) of the chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52444, Nov. 18, 1983]

§ 184.1634 Potassium iodide.

(a) Potassium iodide (KI, CAS Reg. No. 7681-11-0) is the potassium salt of hydriodic acid. It occurs naturally in sea water and is salt deposits, but can be prepared by reacting hydriodic acid (HI) with potassium bicarbonate ($KHCO_3$).

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 246-247, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(d) The ingredient is used in table salt in accordance with § 184.1(b)(2) of this chapter as a source of dietary iodine at a maximum level of 0.01 percent.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1635 Potassium iodate.

(a) Potassium iodate (KIO_3, CAS Reg. No. 7758-05-6) does not occur naturally but can be prepared by reacting iodine with potassium hydroxide.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 245-246, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with § 184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5613, Feb. 14, 1983]

§ 184.1643 Potassium sulfate.

(a) Potassium sulfate (K_2SO_4, CAS Reg. No. 7778-80-5) occurs naturally and consists of colorless or white crystals or crystalline powder having a bitter, saline taste. It is prepared by the neutralization of sulfuric acid with potassium hydroxide or potassium carbonate.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 252, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.015 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1655 Propane.

(a) Propane (empirical formula C_3H_8, CAS Reg. No. 74-98-6) is also known as dimethylmethane or propyl hydrid. It is a colorless, odorless, flammable gas at normal temperatures and pressures. It is easily liquefied under pressure at room temperature and is stored and shipped in the liquid state. Propane is obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The Food and Drug Administration is developing food-grade specifications for propane in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57271, Dec. 29, 1983]

§ 184.1660 Propyl gallate.

(a) Propyl gallate is the *n*-propylester of 3,4,5-trihydroxybenzoic acid ($C_{10}H_{12}O_5$). Natural occurrence of propyl gallate has not been reported. It is commercially prepared by esterification of gallic acid with propyl alcohol followed by distillation to remove excess alcohol.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 257-258, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antioxidant as defined in § 170.3(o)(3) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Good manufacturing practice results in a maximum total content of antioxidants of 0.02 percent of the fat or oil content, including the essential (volatile) oil content, of the food.

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that stated in Part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 44 FR 52826, Sept. 11, 1979; 49 FR 5613, Feb. 14, 1984]

§ 184.1666 Propylene glycol.

(a) Propylene glycol ($C_3H_8O_2$ CAS Reg. No. 57-55-6) is known as 1,2-propanediol. It does not occur in nature. Propylene glycol is manufactured by treating propylene with chlorinated water to form the chlorohydrin which is converted to the glycol by treatment with sodium carbonate solution. It is also prepared by heating glyercol with sodium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 255, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418. It is also available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an anticaking agent as defined in § 170.3(o)(1) of this chapter; antioxidant as defined in § 170.3(o)(3) of this chapter; dough strengthener as defined in § 170.3(o)(6) of this chapter; emulsifier as defined in § 170.3(o)(8) of this chapter; flavor agent as defined in § 170.3(o)(12) of this chapter; formulation aid as defined in § 170.3(o)(14) of this chapter; humectant as defined in § 170.3(o)(16) of this chapter; processing aid as defined in § 170.3(o)(24) of this chapter; solvent and vehicle as defined in § 170.3(o)(27) of this chapter; stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; surface-active agent as defined in § 170.3(o)(29) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 5 percent for alcoholic beverages, as defined in § 170.3(n)(2) of this chapter; 24 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter; 2.5 percent for frozen dairy products as defined in § 170.3(n)(20) of this chapter; 97 percent for seasonings and flavorings as defined in § 170.3(n)(26) of this chapter; 5 percent for nuts and nut products as defined in § 170.3(n)(32) of this chapter; and 2.0 percent for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27812, June 25, 1982]

§ 184.1670 Propylparaben.

(a) Propylparaben is the chemical propyl *p*-hydroxybenzoate. It is produced by the *n*-propanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 258, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1676 Pyridoxine hydrochloride.

(a) Pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HC1$, CAS Reg. No. 58-56-0) is the chemical 3-hydroxy-4,5-dihydroxymethy-2-methylpyridine hydrochloride that is prepared by chemical synthesis.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 260, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter; breakfast cereals as defined in § 170.3(n)(4) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; plant protein products as defined in § 170.3(n)(33) of this chapter; and snack foods as defined in § 170.3(n)(37) of this chapter. Pyridoxine hydrochloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51615, Nov. 10, 1983]

§ 184.1685 Rennet (animal-derived).

(a) Rennet and bovine rennet are commercial extracts containing the active enzyme rennin (CAS Reg. No. 9001-98-3). Rennet is the aqueous extract prepared from cleaned, frozen, salted, or dried fourth stomachs (abomasa) of calves, kids, or lambs. Bovine rennet is the product from adults of the animals listed above. Both products are called rennet and are clear amber to dark brown liquid preparations or white to tan powders.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 107-108, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: In cheeses as defined in § 170.3(n)(5) of this chapter; frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; and milk products as defined in § 170.3(n)(31) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51151, Nov. 7, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1695 Riboflavin.

(a) Riboflavin ($C_{17}H_{20}N_4O_6$, CAS Reg. No. 83-88-5) occurs as yellow to orange-yellow needles that are crystallized from 2*N* acetic acid, alcohol, water, or pyridine. It may be prepared by chemical synthesis, biosynthetically by the organism *Eremothecium ashbyii*, or isolated from natural sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 262, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51148, Nov. 7, 1983]

§ 184.1697 Riboflavin-5′-phosphate (sodium).

(a) Riboflavin-5′-phosphate (sodium) ($C_{17}H_{20}N_4O_9PNa.2H_2O$,CAS Reg. No 130-40-5) occurs as the dihydrate in yellow to orange-yellow crystals. It is prepared by phosphorylation of riboflavin with chlorophosphoric acid, pyrophosphoric acid, metaphosphoric acid, or pyrocatechol cyclic phosphate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 263, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in milk products, as defined in § 170.3(n)(31) of this chapter, at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formulas in accordance with

section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51148, Nov. 7, 1983]

§ 184.1698 Rue.

(a) Rue is the perennial herb of several species of *Ruta* (*Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.). The leaves, buds, and stems from the top of the plant are gathered, dried, and then crushed in preparation for use, or left whole.

(b) The ingredient is used in all categories of food in accordance with § 184.1(b)(2) of this chapter at concentrations not to exceed 2 parts per million.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 3705, Jan. 27, 1978]

§ 184.1699 Oil of rue.

(a) Oil of rue is the natural substance obtained by steam distillation of the fresh blossoming plants of rue, the perennial herb of several species of *Ruta—Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.

(b) Oil of rue meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 266, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Parts per million	Function
Baked goods and baking mixes, § 170.3(n)(1), of this chapter	10	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter
Frozen dairy desserts and mixes, § 170.3 (n)(20) of this chapter	10	Do
Soft candy, § 170.3(n)(38) of this chapter	10	Do
All other food categories	4	Do

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1721 Sodium acetate.

(a) Sodium acetate ($C_2H_3O_2Na$, CAS Reg. No. 127-09-3 or $C_2H_3O_2Na.3H_2O$, CAS Reg. No. 6131-90-4) is the sodium salt of acetic acid and occurs naturally in plant and animal tissues. Sodium acetate may occur in either the anhydrous or trihydrated form. It is produced synthetically by the neutralization of acetic acid with sodium carbonate or by treating calcium acetate with sodium sulfate and sodium bicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 272, 273 which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; and as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.007 percent for breakfast cereals as defined in § 170.3(n)(4) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 0.6 percent for grain products and pastas as defined in § 170.3(n)(23) of this chapter and snack foods as defined in § 170.3(n)(37) of this chapter; 0.15 percent for hard candy as defined in § 170.3(n)(25) of this chapter; 0.12 percent for jams and jellies as defined in § 170.3(n)(28) of this chapter and meat products as defined in § 170.3(n)(29) of this chapter; 0.2 percent for soft candy as defined in § 170.3(n)(38) of this chapter; 0.05 percent for soups and soup mixes as defined in § 170.3(n)(40) of this chapter and sweet sauces as defined in § 170.3(n)(43) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27815, June 25, 1982]

§ 184.1724 Sodium alginate.

(a) Sodium alginate (CAS Reg. No. 9005-38-3) is the sodium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Sodium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 274, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Condiments and relishes, § 170.3(n)(8) of this chapter, except pimento ribbon for stuffed olives.	1.0	Texturizer, § 170.3(o)(32) of this chapter, formulation aid § 170.3(o)(14) of this chapter, stabilizer, thickener, § 170.3(o)(28) of this chapter.
Pimento ribbon for stuffed olives.	6.0	Do.
Confections and frostings, § 170.3(n)(9) of this chapter.	0.3	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Gelatins and puddings, § 170.3(n)(22) of this chapter..	4.0	Firming agent, § 170.3(o)(10) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.
Hard candy, § 170.3(n)(25) of this chapter..	10.0	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter.	2.0	Formulation aid, § 170.3(o)(14) of this chapter; texturizer, § 170.3(o)(32) of this chapter.
All other food categories.	1.0	Emulsifier, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter; procesaing aid, § 170.3(o)(24) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface active agent, § 170.3(o)(29) of this chapter.

(d) Prior sanctions for sodium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982, as amended at 48 FR 52448, Nov. 18, 1983]

§ 184.1733 Sodium benzoate.

(a) Sodium benzoate is the chemical benzoate of soda ($C_7H_5NaO_2$), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide. The salt is not found to occur naturally.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 278, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS.)

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that set forth in Part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1736 Sodium bicarbonate.

(a) Sodium bicarbonate ($NaHCO_3$, CAS Reg. No. 144-55-8) is prepared by treating a sodium carbonate or a sodium carbonate and sodium bicarbonate solution with carbon dioxide. As carbon dioxide is absorbed, a suspension of sodium bicarbonate forms. The slurry is filtered, forming a cake which is washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 278, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1742 Sodium carbonate.

(a) Sodium carbonate (Na_2CO_3, CAS Reg. No. 497-19-8) is produced (1) from purified trona ore that has been calcined to soda ash; (2) from trona ore calcined to impure soda ash and then purified; or (3) synthesized from limestone by the Solvay process.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 280, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an antioxidant as defined in § 170.3(o)(3) of this chapter; curing and pickling agent as defined in § 170.3(o)(5) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1754 Sodium diacetate.

(a) Sodium diacetate ($C_4H_7O_4Na.xH_2O$, CAS Reg. No. 126-96-5) is a molecular compound of acetic acid, sodium acetate, and water of hydration. The technical grade is prepared synthetically by reacting sodium carbonate with acetic acid. Special grades are produced by reacting anhydrous sodium acetate and acetic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 284, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; and pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, 0.4 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.1 percent for fats and oils as defined in § 170.3(n)(12) of this chapter, meat products as defined in § 170.3(n)(29) of this chapter and soft candy as defined in § 170.3(n)(38) of this chapter; 0.25 percent for gravies and sauces as defined in § 170.3(n)(24) of this chapter; and 0.05 percent for snack foods as defined in § 170.3(n)(37) of this chapter and soups and soup mixes as defined in § 170.3(n)(40) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27815, June 25, 1982]

§ 184.1763 Sodium hydroxide.

(a) Sodium hydroxide (NaOH, CAS Reg. No. 1310-73-2) is also known as sodium hydrate, soda lye, caustic soda, white caustic, and lye. The empirical formula is NaOH. Sodium hydroxide is prepared commercially by the electrolysis of sodium chloride solution and also by reacting calcium hydroxide with sodium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52444, Nov. 18, 1983]

§ 184.1764 Sodium hypophosphite.

(a) Sodium hypophosphite (NaH_2PO_2, CAS Reg. No. 7681-53-0) is a white, odorless, deliquescent granular powder with a saline taste. It is also prepared as colorless, pearly crystalline plates. It is soluble in water, alcohol, and glycerol. It is prepared by neutralization of hypophosphorous acid or by direct aqueous alkaline hydrolysis of white phosphorus.

(b) FDA is developing food-grade specifications for sodium hypophosphite in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a suitable purity for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier or stabilizer, as defined in §§ 170.3(o)(8) and 170.3(o)(28) of this chapter.

(2) The ingredient is used in cod-liver oil emulsions at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 38277, Aug. 31, 1982]

§ 184.1769a Sodium metasilicate.

(a) Sodium metasilicate (CAS Reg. No. 6834-92-0) is a strongly alkaline white powder. It does not occur naturally but rather is synthesized by melting sand with sodium carbonate at 1400 °C. The commercially available forms of sodium metasilicate are the anhydrous form (Na_2SiO_3), the pentahydrate ($Na_2SiO_3\ 5H_2O$), and the nonahydrate ($Na_2SiO_3\ 9H_2O$).

(b) FDA is developing food-grade specifications for sodium metasilicate in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used to treat the following foods at levels not to exceed current good manufacturing practice: for use in washing and lye peeling of fruits, vegetables, and nuts when used in accordance with § 173.315 of this chapter; for use as a denuding agent in tripe; for use as a hog scald agent in removing hair; and for use as a corrosion preventative in canned and bottled water when used in accordance with § 103.35 of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 38781, Sept. 25, 1985; 50 FR 42011, Oct. 17, 1985]

§ 184.1784 Sodium propionate.

(a) Sodium propionate ($C_3H_5NaO_2$, CAS Reg. No. 137-40-6) is the sodium salt of propionic acid. It occurs as colorless, transparent crystals or a granular crystalline powder. It is odorless, or has a faint acetic-butyric acid odor, and is deliquescent. It is prepared by neutralizing propionic acid with sodium hydroxide.

(b) The ingredients meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 296, which is incorporated by reference. Copies are available from the the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter and a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; cheeses as defined in § 170.3(n)(5) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; jams and jellies as defined in § 170.3(n)(28) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13142, Apr. 3, 1984]

§ 184.1792 Sodium sesquicarbonate.

(a) Sodium sesquicarbonate ($Na_2CO_3.NaHCO_3 2H_2O$, CAS Reg. No. 533-96-0) is prepared by: (1) Partial carbonation of soda ash solution followed by crystallization, centrifugation, and drying; (2) double refining of trona ore, a naturally occurring impure sodium sesquicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 299, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in cream at levels not to exceed current good manufacturing practice. Current good manufacturing practice utilizes a level of the ingredient sufficient to control lactic acid prior to pasteurization and churning of cream into butter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52443, Nov. 18, 1983]

§ 184.1801 Sodium tartrate.

(a) Sodium tartrate ($C_4H_4Na_2O_6.2H_2O$, CAS Reg. No. 868-18-8) is the disodium salt of L-(+)-tartaric acid. It occurs as transparent, colorless, and odorless crystals. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 303, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in § 170.3(o)(8) of this chapter and as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: cheeses as defined in § 170.3(n)(5) of this chapter; fats and oils as defined in § 170.3(n)(12) of this chapter; and jams and jellies as defined in § 170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52447, Nov. 18, 1983]

§ 184.1804 Sodium potassium tartrate.

(a) Sodium potassium tartrate ($C_4H_4KNaO_6.4H_2O$, CAS Reg. No. 304-59-6) is the sodium potassium salt of L-(+)-tartaric acid and is also called the Rochelle salt. It occurs as colorless crystals or as a white, crystalline powder and has a cooling saline taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 296, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in § 170.3(o)(8) of this chapter and as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: cheeses as defined in § 170.3(n)(5) of this chapter and jams and jellies as defined in § 170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52447, Nov. 18, 1983]

§ 184.1807 Sodium thiosulfate.

(a) Sodium thiosulfate ($Na_2S_2O_3 \cdot 5H_2O$, CAS Reg. No. 010102-17-7) is also known as sodium hyposulfite. It is prepared synthetically by the reaction of sulfides and sulfur dioxide (SO_2), the reaction of sulfur and sulfite, or the oxidation of metal sulfides and hydrosulfides.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 304, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter and reducing agent as defined in § 170.3(o)(22) of this chapter.

(d) The ingredient is used in alcoholic beverages and table salt in accordance with § 184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.00005 percent for alcoholic beverages as defined in § 170.3(n)(2) of this chapter and 0.1 percent for table salt as defined in § 170.3(n)(26) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 22938, May 30, 1978, as amended at 49 FR 5613, Feb. 4, 1984]

§ 184.1835 Sorbitol.

(a) Sorbitol is the chemical 1,2,3,4,5,6-hexanehexol ($C_6H_{14}O_6$), a hexahydric alcohol, differing from mannitol principally by having a different optical rotation. Sorbitol is produced by the electrolytic reduction, or the transition metal catalytic hydrogenation of sugar solutions containing glucose or fructose.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 308, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in § 170.3(o)(1) of this chapter, curing and pickling agent as defined in § 170.3(o)(5) of this chapter, drying agent as defined in § 170.3(o)(7) of this chapter, emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, humectant as defined in § 170.3(o)(16) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, nutritive sweetener as defined in § 170.3(o)(21) of this chapter, sequestrant as defined in § 170.3(o)(26) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, surface-finishing agent as defined in § 170.3(o)(30) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice in the use of sorbitol results in a maximum level of 99 percent in hard candy and cough drops as defined in § 170.3(n)(25) of this chapter, 75 percent in chewing gum as defined in § 170.3(n)(6) of this chapter, 98 percent in soft candy as defined in § 170.3(n)(38) of this chapter, 30 percent in nonstandardized jams and jellies, commercial, as defined in § 170.3(n)(28) of this chapter, 30 percent in baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter, 17 percent in frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, and 12 percent in all other foods.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 50 grams of sorbitol shall bear the statement: "Excess consumption may have a laxative effect."

(f) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§184.1845 Stannous chloride (anhydrous and dihydrated).

(a) Stannous chloride is anhydrous or contains two molecules of water of hydration. Anhydrous stannous chloride ($SnCl_2$, CAS Reg. No. 7772-99-8) is the chloride salt of metallic tin. It is prepared by reacting molten tin with either chlorine or gaseous tin tetrachloride. Dihydrated stannous chloride ($SnCl_2 \cdot 2H_2O$, CAS Reg. No. 10025-69-1) is the chloride salt of metallic tin that contains two molecules of water. It is prepared from granulated tin suspended in water and hydrochloric acid or chlorine.

(b) Both forms of the ingredient meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 312, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antioxidant as defined in § 170.3(o)(3) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.0015 percent or less; calculated as tin, for all food categories.

(e) Prior sanctions for this ingredient different from those uses established in this section do not exist or have been waived.

[47 FR 27816, June 25, 1982]

§ 184.1848 Starter distillate.

(a) Starter distillate (butter starter distillate) is a steam distillate of the culture of any or all of the following species of bacteria grown on a medium consisting of skim milk usually fortified with about 0.1 percent citric acid: *Streptococcus lactis, S. cremoris, S. lactis subsp. diacetylactis, Leuconostoc citrovorum,* and *L. dextranicum.* The ingredient contains more than 98 percent water, and the remainder is a mixture of butterlike flavor compounds. Diacetyl is the major flavor component, constituting as much as 80 to 90 percent of the mixture of organic flavor compounds. Besides diacetyl, starter distillate contains minor amounts of acetaldehyde, ethyl formate, ethyl acetate, acetone, ethyl alcohol, 2-butanone, acetic acid, and acetoin.

(b) FDA is developing food-grade specifications for starter distillate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51907, Nov. 15, 1983]

§ 184.1875 Thiamine hydrochloride.

(a) Thiamine hydrochloride ($C_{12}H_{17}ClN_4OS.HCl$, CAS Reg. No. 67-03-8) is the chloride-hydrochloride salt of thiamine. It occurs as hygroscopic white crystals or a white crystalline powder. The usual method of preparing this substance is by linking the preformed thiazole and pyrimidine ring systems.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 324, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter or as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Thiamine hydrochloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 55124, Dec. 9, 1983]

§ 184.1878 Thiamine mononitrate.

(a) Thiamine mononitrate ($C_{12}H_{17}N_5O_4S$, CAS Reg. No. 532-43-4) is the mononitrate salt of thiamine. It occurs as white crystals or a white crystalline powder and is prepared from thiamine hydrochloride by dissolving the hydrochloride salt in alkaline solution followed by precipitation of the nitrate half-salt with a stoichiometric amount of nitric acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 325, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Thiamine mononitrate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 55124, Dec. 9 1983]

§ 184.1890 *α*-Tocopherols.

(a) The *α*-tocopherols that are the subject of this GRAS affirmation regulation are limited to the following:

(1) *d*-*α*-Tocopherol (CAS Reg. No. 59-02-9) is the chemical [2R,4′R,8′R]-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyl-tridecyl)-6-chromanol. It occurs commercially as a concentrate and is a red, nearly odorless, viscous oil. It is obtained by vacuum steam distillation of edible vegetable oil products.

(2) *dl*-α-Tocopherol (CAS Reg. No. 10191-41-0) is a mixture of stereoisomers of 2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyl-tridecyl)-6-chromanol. It is chemically synthesized by condensing racemic isophytol with trimethyl hydroquinone. It is a pale yellow viscous oil at room temperature.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 330-331, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L. St. NW., Washington, DC 20408..

(c) In accordance with § 184.1(b)(3), the affirmation of the ingredients as generally recognized as safe is limited to the following conditions of use while the agency concludes the general evaluation of all food uses of tocopherols:

(1) The ingredients are used as inhibitors of nitrosamine formation.

(2) The ingredients are used in pump-cured bacon at levels not to exceed current good manufacturing practice.

[49 FR 13348, Apr. 4, 1984]

§ 184.1923 Urea.

(a) Urea ($CO(NH_2)_2$, CAS Reg. No. 57-13-6) is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis.

(b) FDA is developing food-grade specifications for urea in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter and as a fermentation aid.

(2) The ingredient is used in yeast-raised bakery products; in alcoholic beverages as defined in § 170.3(n)(2) of this chapter; and in gelatin products.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51616, Nov. 10, 1983, as amended at 49 FR 19816, May 10, 1984]

§ 184.1930 Vitamin A.

(a)(1) Vitamin A (retinol; CAS Reg. No. 68-26-8) is the alcohol 9,13-dimethyl-7-(1,1,5-trimethyl-6-cyclohexen-5-yl)-7,9,11,13-nonatetraen-15-ol. It may be nearly odorless or have a mild fishy odor. Vitamin A is extracted from fish liver oils or produced by total synthesis from β-ionone and a propargyl halide.

(2) Vitamin A acetate (retinyl acetate; CAS Reg. No. 127-47-9) is the acetate ester of retinol. It is prepared by esterifying retinol with acetic acid.

(3) Vitamin A palmitate (retinyl palmitate; CAS Reg. No. 79-81-2) is the palmitate ester of retinol. It is prepared by esterifying retinol with palmitic acid.

(b) The ingredient meets the specifications for vitamin A in the Food Chemicals Codex, 3d Ed. (1981), p. 342, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. Vitamin A may be used in infant formula in accordance

with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51610, Nov. 10, 1983]

§ 184.1945 Vitamin B_{12}.

(a) Vitamin B_{12}, also known as cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$, CAS Reg. No. 68-19-9), is produced commercially from cultures of *Streptomyces griseus.*

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 343, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Vitamin B_{12} also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 6341, Feb. 15, 1985]

§ 184.1950 Vitamin D.

(a) Vitamin D is added to food as the following food ingredients:

(1) Crystalline vitamin D_2 ($C_{28}H_{44}O$, CAS Reg. No. 50-14-6), also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. The ingredient is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization.

(2) Crystalline vitamin D_3 ($C_{27}H_{44}O$, CAS Reg. No. 67-97-0), also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E,)-5,7,10(19)-cholestatrien-3-ol. Vitamin D_3 occurs in, and is isolated from, fish liver oils. It is also manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol. It is purified by crystallization. Vitamin D_3 is the vitamin D form that is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.

(3) Vitamin D_2 resin and vitamin D_3 resin are the concentrated forms of irradiated ergosterol (D_2) and irradiated 7-dehydrocholesterol (D_3) that are separated from the reacting materials in paragraphs (a) (1) and (2) of this section. The resulting products are sold as food sources of vitamin D without further purification.

(b) Vitamin D_2 and vitamin D_3 as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. FDA is developing food-grade specifications for vitamin D_2 resin and vitamin D_3 resin in cooperation with the National Academy of Sciences. In the interim, these resins must be of a purity suitable for their intended use.

(c)(1) In accordance with § 184.1(b)(2), the ingredients are used in food as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served)	Functional use
Breakfast cereals, § 170.3(n)(4) of this chapter	350 (IU/100 grams)	Nutrient supplement, § 170.3(o)(20) of this chapter

Category of food	Maximum levels in food (as served)	Functional use
Grain products and pastas. § 170 3(n)(23) of this chapter	90(IU/100 grams)	Do
Milk, § 170 3(n)(30) of this chapter	42 (IU/100 grams)	Do
Milk products, § 170 3(n)(31) of this chapter	89 (IU/100 grams)	Do

(2) Vitamin D may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(3) Vitamin D may be used in margarine in accordance with § 166.110 of this chapter.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[50 FR 30152, July 24, 1985]

§ 184.1973 Beeswax (yellow and white).

(a) Beeswax (CAS Reg. No. 8012-89-3) is a secretory product of honey bees used as a structural material in honeycombs. Beeswax is prepared from honeycombs after removal of the honey by draining or centrifuging. The combs are melted in hot water or steam or with solar heat, and strained. The wax is refined by melting in hot water to which sulfuric acid or alkali may be added to extract impurities. The resulting wax is referred to as yellow beeswax. White beeswax is produced by bleaching the constituent pigments of yellow beeswax with peroxides, or preferably it is bleached by sun light.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 34-35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, as a lubricant as defined in § 170.3(o)(18) of this chapter, and as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(d) The ingredient is used in food, in accordance with § 184.1(b)(1) of this chapter, at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of: 0.065 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 0.005 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter; 0.04 percent for hard candy as defined in § 170.3(n)(25) of this chapter; 0.1 percent for soft candy as defined in § 170.3(n)(38) of this chapter, and 0.002 percent or less for all other food categories.

[43 FR 14644, Apr. 7, 1978, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 49536, Dec. 3, 1985]

§ 184.1976 Candelilla wax.

(a) Candelilla wax (CAS Reg. No. 8006-44-8) is obtained from the candelilla plant. It is a hard, yellowish-brown, opaque-to-translucent wax. Candelilla wax is prepared by immersing the plants in boiling water containing sulfuric acid and skimming off the wax that rises to the surface. It is composed of about 50 percent hydrocarbons with smaller amounts of esters and free acids.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 67, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant as defined in § 170.3(o)(18) of this chapter and as a surface-finishing

agent as defined in § 170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: in chewing gum as defined in § 170.3(n)(6) of this chapter and in hard candy as defined in § 170.3(n)(25) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51617, Nov. 10, 1983]

§ 184.1978 Carnauba wax.

(a) Carnauba wax (CAS Reg. No. 008-015-869) is obtained from the leaves and buds of the Brazilian wax palm *Copernicia cerifera* Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water. It is marketed in five grades designated No. 1 through No. 5. Grades No. 4 and No. 5 represent the bulk of the commercial trade volume. These commercial grades consist chiefly of C_{24} to C_{32} normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking agent as defined § 170.3(o)(1) of this chapter; as a formulation aid as defined in § 170.3(o)(14) of this chapter; as a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; and as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter; chewing gun as defined in § 170.3(n)(6) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; fresh fruits and fruit juices as defined in § 170.3(n)(16) of this chapter; gravies and sauces as defined in § 170.3(n)(24) of this chapter; processed fruits and fruit juices as defined in § 170.3(n)(35) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51147, Nov. 7, 1983]

§ 184.1979 Whey.

(a)(1) *Whey.* Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking. Whey obtained from a procedure, in which a significant amount of lactose is converted to lactic acid, or from the curd formation by direct acidification of milk, is known as acid whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Sweet whey has a maximum titratable acidity of not more than 0.16 percent, calculated as lactic acid, and an alkalinity of ash of not more than 225 milliliters of 0.1*N* hydrochloric acid per 100 grams. The acidity of whey, sweet or acid, may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(2) *Concentrated whey.* Concentrated whey is the liquid substance obtained by the partial removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(3) *Dry or dried whey.* Dry or dried whey is the dry substance obtained by the removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(b) The ingredients meet the following specifications:

(1) The analysis of whey, concentrated whey, and dry (dried) whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, 10 to 15 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 0.2 to 2.0 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 7 to 14 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, 61 to 75 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 8 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead). Not more than 10 parts per million (0.001 percent) as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512-513,[1] which is incorporated by reference.

(3) The whey must be derived from milk that has been pasteurized, or the whey and modified whey product must be subjected to pasteurization techniques or its equivalent before use in food.

(c) Whey, concentrated whey, and dry (dried) whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The label on the whey form sold to food manufacturers shall read as follows:

(1) For whey: "(Sweet or acid) whey" or "whey (——% titratable acidity).

(2) For concentrated whey: "Concentrated (sweet or acid) whey, ——% solids" or "Concentrated whey (——% titratable acidity), ——% solids".

(3) For dry (dried) whey: "Dry (dried) (sweet or acid) whey" or "dry (dried) whey, (——% titratable acidity)".

(e) Whey, concentrated whey, or dry (dried) whey in a finished food product shall be listed as "whey."

[46 FR 44439, Sept. 4, 1981; 47 FR 7410, Feb. 19, 1982]

§ 184.1979a Reduced lactose whey.

(a) Reduced lactose whey is the substance obtained by the removal of lactose from whey. The lactose content of the finished dry product shall not exceed 60 percent. Removal of the lactose is accomplished by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced lactose whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced lactose whey may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(b) The reduced lactose whey meets the following specifications:

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, 16 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 11 to 27 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, not more than 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the method prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512-513,[1] which is incorporated by reference.

(3) The reduced lactose whey shall be derived from milk that has been pasteurized, or the reduced lactose whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) Reduced lactose whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of lactose present on a dry product basis, i.e., "reduced lactose whey (——% lactose)", shall be declared on the label of the package sold to food manufacturers. The percent of lactose may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of lactose in the product, or as a actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(e) The presence of reduced lactose whey in a finished food product shall be listed as "reduced lactose whey."

[46 FR 44440, Sept. 4, 1981]

§ 184.1979b Reduced minerals whey.

(a) Reduced minerals whey is the substance obtained by the removal of a portion of the minerals from whey. The dry product shall not contain more than 7 percent ash. Reduced minerals whey is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced minerals whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced minerals whey may be adjusted by the additional of safe and suitable pH-adjusting ingredients.

(b) The reduced minerals whey meets the following specifications:

(1) The analysis of reduced minerals whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists, 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, 10 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, maximum 7 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, maximum 85 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solid."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512-513,[1] which is incorporated by reference.

(3) The reduced minerals whey shall be derived from milk that has been pasteurized, or the reduced minerals whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The reduced minerals whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of minerals present on a dry product basis, i.e.,

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

"reduced minerals whey (—% minerals)", shall be declared on the label of the package sold to food manufacturers. The percent of minerals may be declared in 2-percent increments expressed as a multiple of 2, not greater than the actual percentage of minerals in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of reduced minerals whey in a finished food product shall be listed as "reduced minerals whey".

[46 FR 44441, Sept. 4, 1981]

§ 184.1979c Whey protein concentrate.

(a) Whey protein concentrate is the substance obtained by the removal of sufficient nonprotein constituents from whey so that the finished dry product contains not less than 25 percent protein. Whey protein concentrate is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, whey protein concentrate can be used as a fluid, concentrate, or dry product form. The acidity of whey protein concentrate may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The whey protein concentrate meets the following specifications:

(1) The analysis of whey protein concentrate, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980),[2] which is incorporated by reference, is:

(i) Protein content, minimum 25 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Officials Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 1 to 10 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 2 to 15 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, maximum 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are:

Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the Food Chemicals Codex, 3d ed. (1981), pp. 512-513,[1] which is incorporated by reference.

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(3) The whey protein concentrate shall be derived from milk that has been pasteurized, or the whey protein concentrate shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The whey protein concentrate may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of protein present on a dry product basis, i.e., "whey protein concentrate (——% protein)", shall be declared on the label of the package sold to food manufacturers. The percent of protein may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of protein in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of whey protein concentrate in a finished food product shall be listed as "whey protein concentrate".

[46 FR 44441, Sept. 4, 1981]

§ 184.1983 Bakers yeast extract.

(a) Bakers yeast extract is the food ingredient resulting from concentration of the solubles of mechanically ruptured cells of a selected strain of yeast, *Saccharomyces cerevisiae*. It may be concentrated or dried.

(b) The ingredient meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient as a concentrate or dry material is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter at a level not to exceed 5 percent in food.

(e) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

§ 184.1984 Zein.

(a) Zein (CAS Reg. No. 9010-66-6) is one of the components of corn gluten. It is produced commercially by extraction from corn gluten with alkaline aqueous isopropyl alcohol containing sodium hydroxide. The extract is then cooled, which causes the zein to precipitate.

(b) FDA is developing food-grade specifications for zein in cooperation with the National Academy of Sciences. In the interim, the igredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8999, Mar. 6, 1985]

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.
186.1 Substances added indirectly to human food affirmed as generally recognized as safe (GRAS).

Subpart B—Listing of Specific Substances Affirmed as GRAS

186.1025 Caprylic acid.
186.1093 Sulfamic acid.

Sec.
186.1256 Clay (kaolin).
186.1275 Dextrans.
186.1316 Formic acid.
186.1551 Hydrogenated fish oil.
186.1557 Tall oil.
186.1673 Pulp.
186.1750 Sodium chlorite.
186.1756 Sodium formate.
186.1770 Sodium oleate.
186.1771 Sodium palmitate.
186.1797 Sodium sulfate.
186.1839 Sorbose.

AUTHORITY: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

SOURCE: 42 FR 14658, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 186.1 Substances added indirectly to human food affirmed as generally recognized as safe (GRAS).

(a) The indirect human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed, providing they comply with the purity specifications listed in this part or, in the absence of purity specifications, are of a purity suitable for their intended use in accordance with § 170.30(h)(1) of this chapter. Certain ingredients in this part may also be used in food-contact surfaces in accordance with Parts 174, 175, 176, 177, 178 or § 179.45 of this chapter. Ingredients affirmed as GRAS for direct use in Part 184 of this chapter are also GRAS as indirect human food ingredients in accordance with § 184.1(a) of this chapter.

(b) The regulations in this part do not authorize direct addition of any food ingredient to a food. They authorize only the use of these ingredients as indirect ingredients of food, through migration from their immediate wrapper, container, or other food-contact surface. Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practice. For the purpose of this part, current good manufacturing practice includes the requirements that an indirect human food ingredient be of a purity suitable for its intended use, and that it be used at a level no higher than reasonably required to achieve its intended technical effect in the food-contact article.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraphs (b), (c), and (d) of this section. When the Food and Drug Administration (FDA) determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the indirect ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the indirect ingredient, one or more of these limited conditions of use, which may include the category of food-contact surface(s), technical effect(s) or functional use(s) of the indirect ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, such use of a substance may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that the use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with § 170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food-contact surfaces only within such limitation(s), including the category of food-contact surface(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, prior to general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this part does not authorize the use of such substance for the purpose of adding the ingredient to the food through extraction from the food-contact surface.

(d) The listing of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception to the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under Part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

[42 FR 14658, Mar. 15, 1977, as amended at 48 FR 48457, 48459, Oct. 19, 1983]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 186.1025 Caprylic acid.

(a) Caprylic acid [$CH_3(CH_2)_6COOH$, CAS Reg. No. 124-07-2] is the chemical name for octanoic acid. It is considered to be a short or medium chain fatty acid. It occurs normally in various foods and is commercially prepared by oxidation of *n*-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 207, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The ingredient is used as an antimicrobial (preservative) in cheese wraps as defined in § 170.3(o)(2) at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 19843, May 9, 1978, as amended at 49 FR 5613, Feb. 14, 1984]

§ 186.1093 Sulfamic acid.

(a) Sulfamic acid (H_3NO_3S, CAS Reg. No. 5329-14-6) is a white crystalline solid manufactured from urea, sulfur trioxide, and sulfuric acid. It is soluble and highly ionized in water.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect food ingredient with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the current good manufacturing practice of using this ingredient in the manufacture of paper and paperboard that contact food.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29954, July 9, 1982]

§ 186.1256 Clay (kaolin).

(a) Clay (kaolin) $Al_2O_{3\cdot 2SiO_2\cdot nH_2}O$, Cas Reg. No. 1332-58-7) consists of hydrated aluminum silicate. The commercial products of clay (kaolin) contain varying quantities of alkalies and alkaline earths. Clay (kaolin) is a white to yellowish or grayish fine powder. There are at least three different minerals, kaolinite, dickite, and nacrite, classified as kaolin. Kaolinite or china clay is whiter, less contaminated with extraneous minerals, and less plastic in water.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in the manufacture of paper and paperboard that contact food.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[47 FR 43367, Oct. 1, 1982]

§ 186.1275 Dextrans.

(a) Dextrans (CAS Reg. No. 9004-54-0) are high molecular weight polysaccharides produced by bacterial fermentation of sucrose. Commercially available dextrans are synthesized from sucrose by *Leuconostoc mesenteroides* strain NRRL B-512(F). Partial depolymerization and purification of the fermented mixture shall produce a product that is free of viable microorganisms.

(b) The ingredient is used or intended for use as a constituent of food-contact surfaces.

(c) The ingredient is used at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 29288, July 7, 1978, as amended at 48 FR 48457, Oct. 19, 1983]

§ 186.1316 Formic acid.

(a) Formic acid (CH_2O_2, CAS Reg. No. 64-18-6) is also referred to as methanoic acid or hydrogen carboxylic acid. It occurs naturally in some insects and is contained in the free acid state in a number of plants. Formic acid is prepared by the reaction of sodium formate with sulfuric acid and is isolated by distillation.

(b) Formic acid is used as a constituent of paper and paperboard used for food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for formic acid different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980]

§ 186.1551 Hydrogenated fish oil.

(a) Hydrogenated fish oil (CAS Reg. No. 8016-14-6) is a class of oils produced by partial hydrogenation of oils expressed from fish, primarily menhaden, and secondarily herring or tuna. Hydrogenation of fish oils uses catalysts composed of either elemental nickel, elemental copper, or a mixture of these elements. The crude hydrogenated fish oil is further processed by alkali refining, bleaching, and deodorization by steam stripping.

(b) Hydrogenation of fish oils results in a final product with a melting point greater than 32° C as determined by Section Cc 1-25, Official and Tentative Methods of the American Oil Chemists' Society method (reapproved 1973) or equivalent. The product has an approximate fatty acid composition of 30 to 45 percent saturated fatty acids, 40 to 55 percent monoenoic fatty acids, 7 to 15 percent dienoic fatty acids, 3 to 10 percent trienoic fatty acids, and less than 2 percent tetraenoic or higher polyenoic fatty acids. The approximate percentages of total fatty acids by carbon chain length are 15 to 30 percent each of C_{16}, C_{18}, C_{20}, C_{22}, less than 10 percent C_{14} or lower carbon chain length, and less than 1 percent C_{24} or higher carbon chain length fatty acids.

(c) The ingredient is used as a constituent of cotton and cotton fabrics used for dry food packaging.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(e) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[44 FR 28323, May 15, 1979, as amended at 49 FR 5614, Feb. 14, 1984]

§ 186.1557 Tall oil.

(a) Tall oil (CAS Reg. No. 8002-26-4) is essentially the sap of the pine tree. It is obtained commercially from the waste liquors of pinewood pulp mills and consists mainly of tall oil resin acids and tall oil fatty acids.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based on the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of cotton and cotton fabrics used for dry food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section, or from those listed in Part 181 of this chapter, do not exist or have been waived.

[51 FR 16830, May 7, 1986]

§ 186.1673 Pulp.

(a) Pulp is the soft, spongy pith inside the stem of a plant such as wood, straw, sugarcane, or other natural plant sources.

(b) The ingredient is used or intended for use as a constituent of food packaging containers.

(c) The ingredient is used in paper and paperboard made by conventional paper-making processes at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 186.1750 Sodium chlorite.

(a) Sodium chlorite ($NaClO_2$, CAS Reg. No. 7758-19-2) exists as slightly hygroscopic white crystals or flakes. It is manufactured by passing chlorine dioxide into a solution of sodium hydroxide and hydrogen peroxide.

(b) the ingredient is used at levels from 125 to 250 parts per million as a slimicide in the manufacture of paper and paperboard that contact food.

[45 FR 16470, Mar. 14, 1980]

§ 186.1756 Sodium formate.

(a) Sodium formate ($CHNaO_2$, CAS Reg. No. 141-53-7) is the sodium salt of formic acid. It is produced by the reaction of carbon monoxide with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for sodium formate different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980]

§ 186.1770 Sodium oleate.

(a) Sodium oleate ($C_{18}H_{33}O_2Na$, CAS Reg. No. 143-19-1) is the sodium salt of oleic acid (*cis*-9-octadecenoic acid). It exists as a white to yellowish powder with a slight tallow-like odor. Commercially, sodium oleate is made by mixing and heating flaked sodium hydroxide and oleic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging and as a component of lubricants with incidental food contact in accordance with § 178.3570 of this chapter, with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1771 Sodium palmitate.

(a) Sodium palmitate ($C_{16}H_{31}O_2Na$, CAS Reg. No. 408-35-5) is the sodium salt of palmitic acid (hexadecanoic acid). It exists as a white to yellow powder. Commercially, sodium palmitate is made by mixing and heating flaked sodium hydroxide and palmitic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na_2SO_4, CAS Reg. No. 7757-82-6), also known as Glauber's salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980]

§ 186.1839 Sorbose.

(a) Sorbose (L-sorbose, sorbinose) ($C_6H_{12}O_6$, CAS Reg. No. 87-79-6) is an orthorhombic, bisphenoidal crystalline ketohexose. It was originally identifed in the juice of mature berries from the mountain ash (*Sorbus aucuparia*) where it occurs as the result of microbial oxidation of sorbitol. It also occurs naturally in other plants. Sorbose can be synthesized by the catalytic hydrogenation of glucose to D-sorbitol. The resulting sorbitol can be oxidized by *Acetobacter xylinum* or by *Acetobacter suboxydans.*

(b) The ingredient is used or intended for indirect food use as a constituent of cotton, cotton fabrics, paper, and paperboard in contact with dry food.

(c) The ingredient migrates to food at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11698, Mar. 21, 1978, as amended at 48 FR 48457, Oct. 19, 1983]

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

Subpart A—General Provisions

Sec.
189.1 Substances prohibited from use in human food.

Subpart B—Substances Generally Prohibited From Direct Addition or Use as Human Food

189.110 Calamus and its derivatives.
189.113 Cinnamyl anthranilate.
189.120 Cobaltous salts and its derivatives.
189.130 Coumarin.
189.135 Cyclamate and its derivatives.
189.140 Diethylpyrocarbonate (DEPC).
189.145 Dulcin.
189.155 Monochloroacetic acid.
189.165 Nordihydroguaiaretic acid (NDGA).
189.175 P-4000.
189.180 Safrole.
189.190 Thiourea.
189.191 Chlorofluorocarbon propellants.

Subpart C—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

189.220 Flectol H.
189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.
189.280 4,4'-Methylenebis (2-chloroanaline).

AUTHORITY: Secs. 201(s) 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, unless otherwise noted.

SOURCE: 42 FR 14659, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to Part 2 of this chapter, and will be published for comment if it contains reasonable grounds.

Subpart B—Substances Generally Prohibited From Direct Addition or Use as Human Food

§ 189.110 Calamus and its derivatives.

(a) Calamus is the dried rhizome of *Acorus calamus* L. It has been used as a flavoring compound, especially as the oil or extract.

(b) Food containing any added calamus, oil of calamus, or extract of calamus is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of May 9, 1968 (33 FR 6967).

(c) The analytical method used for detecting oil of calamus (β-asarone) is in the *Journal of the Association of Official Analytical Chemists*, Volume 56, (Number 5), pages 1281 to 1283, September 1973, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, also from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 47 FR 11855, Mar. 19, 1982]

§ 189.113 Cinnamyl anthranilate.

(a) The food additive cinnamyl anthranilate ($C_{16}H_{15}NO_2$, CAS Reg. No. 87-29-6) is the ester of cinnamyl alcohol and anthranilic acid. Cinnamyl anthranilate is a synthetic chemical that has not been identified in natural products at levels detectable by available methodology. It has been used as a flavoring agent in food.

(b) Food containing any added cinnamyl anthranilate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 23, 1985.

[50 FR 42932, Oct. 23, 1985]

§ 189.120 Cobaltous salts and its derivatives.

(a) Cobaltous salts are the chemicals, $CoC_4H_6O_4$, $CoCl_2$, and $CoSO_4$. They have been used in fermented malt beverages as a foam stabilizer and to prevent "gushing."

(b) Food containing any added cobaltous salts is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 12, 1966 (31 FR 8788).

§ 189.130 Coumarin.

(a) Coumarin is the chemical 1,2-benzopyrone, $C_9H_6O_2$. It is found in tonka beans and extract of tonka beans, among other natural sources, and is also synthesized. It has been used as a flavoring compound.

(b) Food containing any added coumarin as such or as a constituent of tonka beans or tonka extract is deemed to be adulterated under the act, based upon an order published in the FEDERAL REGISTER of March 5, 1954 (19 FR 1239).

(c) The analytical methods used for detecting coumarin in food are in sections 19.016-19.024 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.135 Cyclamate and its derivatives.

(a) Calcium, sodium, magnesium and potassium salts of cyclohexane sulfamic acid, $(C_6H_{12}NO_3S)_2Ca$, $(C_6H_{12}NO_3S)Na$, $(C_6H_{12}NO_3S)_2$ Mg, and $(C_6H_{12}NO_3S)K$. Cyclamates are synthetic chemicals having a sweet taste 30 to 40 times that of sucrose, are not found in natural products at levels detectable by the official methodology, and have been used as artificial sweeteners.

(b) Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 21, 1969 (34 FR 17063).

(c) The analytical methods used for detecting cyclamate in food are in sections 20.162-20.172 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.140 Diethylpyrocarbonate (DEPC).

(a) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, $C_6H_{10}O_5$. It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and nonalcoholic beverages.

(b) Food containing any added or detectable level of DEPC is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

§ 189.145 Dulcin.

(a) Dulcin is the chemical 4-ethoxyphenylurea, $C_9H_{12}N_2O_2$. It is a synthetic chemical having a sweet taste about 250 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of dulcin is deemed to be adulterated in violation of the act, based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting dulcin in food are in sections 20.173-20.176 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.155 Monochloroacetic acid.

(a) Monochloroacetic acid is the chemical chloroacetic acid, $C_2H_3ClO_2$. It is a synthetic chemical not found in natural products, and has been proposed as a preservative in alcoholic and nonalcoholic beverages. Monochloroacetic acid is permitted in food package adhesives with an accepted migration level up to 10 parts per billion (ppb) under § 175.105 of this chapter. The official methods do not detect monochloroacetic acid at the 10 ppb level.

(b) Food containing any added or detectable level of monochloroacetic acid is deemed to be adulterated in violation of the act based upon trade correspondence dated December 29, 1941 (TC-377).

(c) The analytical methods used for detecting monochloroacetic acid in food are in sections 20.067-20.072 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.165 Nordihydroguaiaretic acid (NDGA).

(a) Nordihydroguaiaretic acid is the chemical 4,4'-(2,3-dimethyltetramethylene) dipyrocatechol, $C_{18}H_{22}O_4$. It occurs naturally in the resinous exudates of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods.

(b) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 11, 1968 (33 FR 5619).

(c) The analytical method used for detecting NDGA in food is in section 20.008(b) of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.175 P-4000.

(a) P-4000 is the chemical 5-nitro-2-n-propoxyaniline, $C_9H_{12}N_2O_3$. It is a synthetic chemical having a sweet taste about 4000 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of P-4000 is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting P-4000 in food are in sections 20.177-20.181 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.180 Safrole.

(a) Safrole is the chemical 4-allyl-1,2-methylenedioxy-benzene, $C_{10}H_{10}O_2$.

It is a natural constituent of the sassafras plant. Oil of sassafras is about 80 percent safrole. Isosafrole and dihydrosafrole are derivatives of safrole, and have been used as flavoring compounds.

(b) Food containing any added safrole, oil of sassafras, isosafrole, or dihydrosafrole, as such, or food containing any safrole, oil of sassafras, isosafrole, or dihydrosafrole, e.g., sassafras bark, which is intended solely or primarily as a vehicle for imparting such substances to another food, e.g., sassafras tea, is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 3, 1960 (25 FR 12412).

(c) The analytical method used for detecting safrole, isosafrole and dihydrosafrole is in the *Journal of the Association of Official Analytical Chemists*, Volume 54 (Number 4), pages 900 to 902, July 1971, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 42 FR 56729, Oct. 28, 1977; 47 FR 11855, Mar. 19, 1982]

§ 189.190 Thiourea.

(a) Thiourea is the chemical thiocarbamide, CH_4N_2S. It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antimycotic for use in dipping citrus.

(b) Food containing any added or detectable level of thiourea is deemed to be adulterated under the act.

(c) The analytical methods used for detecting thiourea are in sections 20.115-20.126 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984]

§ 189.191 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human food as propellants in self-pressurized containers is prohibited as provided by § 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

Subpart C—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

§ 189.220 Flectol H.

(a) Flectol H is the chemical 1,2-dihydro-2,2,4-trimethylquinoline, polymerized, $C_{12}H_{17}N$. It is a synthetic chemical not found in natural products, and has been used as a component of food packaging adhesives.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 7, 1967 (32 FR 5675).

§ 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.

(a) Mercaptoimidazoline and 2-mercaptoimidazoline both have the molecular formula $C_3H_6N_2S$. They are synthetic chemicals not found in natural products and have been used in the production of rubber articles that may come into contact with food.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of November 30, 1973 (38 FR 33072).

§ 189.280 4,4′-Methylenebis (2-chloroanaline).

(a) 4,4′-Methylenebis (2-chloroanaline) has the molecular formula, $C_{13}H_{12}Cl_2N_2$. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 2, 1969 (34 FR 19073).

PART 193—TOLERANCES FOR PESTICIDES IN FOOD ADMINISTERED BY THE ENVIRONMENTAL PROTECTION AGENCY

Subpart A—Food Additives Permitted in Food for Human Consumption

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Subpart B—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

193.520 Malathion.

AUTHORITY: Sec. 409, 72 Stat. 1785 (21 U.S.C. 348), unless otherwise noted.

SOURCE: 40 FR 14156, Mar. 28, 1975, unless otherwise noted. Redesignated at 41 FR 26568, June 28, 1976.

EDITORIAL NOTE: The full text of this part, transferred from former Part 121, was set out under Part 123 in the tenth recodification document published at 40 FR 14156, Mar. 28, 1975. Part 123 was subsequently transferred to Part 193 at 41 FR 26568, June 28, 1976.

Subpart A—Food Additives Permitted in Food for Human Consumption

§ 193.10 Acephate.

(a) A food additive tolerance of 0.02 ppm is established for the combined residues of acephate (*O,S*-dimethyl acetylphosphoramidothioate) and its cholinesterase-inhibiting metabolite, methamidophos as follows:

(1) In or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments.

(2) The acephate may be present as a residue from applications of acephate in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries in accordance with the following prescribed conditions:

(i) Application shall be limited solely to spot and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared and served. Spray concentration shall be limited to a maximum of 1.0 percent active ingredient. For crack and crevice treatments, equipment capable of delivering a pin-stream of insecticide shall be used. For spot treatments, a coarse, low-pressure spray shall be used to avoid atomization or splashing of the spray. Contamination of food or food-contact surfaces shall be avoided.

(ii) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such lable and labeling.

[47 FR 52995, Nov. 24, 1982]

§ 193.15 Aldicarb.

(a) A regulation is established permitting the combined residues of the insecticide/nematocide aldicarb 2-methyl-2-(methylthio)propionaldehyde *O*-(methylcarbamoyl)oxime and its cholinesterase-inhibiting metabolites 2-methyl-2-(methylsulfonyl) propionaldehyde *O*-(methylcarbamoyl)oxime and 2-methyl-2-(methylsulfonyl)propionaldehyde *O*-(methylcarbamoyl)oxime in or on the commodity sorghum bran at 0.5 part per million.

(b) A regulation is established permitting the combined residues of aldicarb and the above metabolites in or on the commodity dried hops at 50 parts per million resulting from the application of the insecticide in accordance with the provisions of an experimental use permit that expires June 5, 1982. This temporary food additive regulation also expires June 5, 1982.

(1) Residues in or on dried hops not in excess of 50 parts per million resulting from the use described in paragraph (b) of this section remaining after expiration of the experimental

use program will not be considered actionable if the insecticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and food additive tolerance.

(2) Washington State University will immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The university will also keep records of distribution and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

(3) To assure safe use of the additive, its label and labeling shall conform to that approved by the EPA in conjunction with the issuance of the experimental use permit.

[47 FR 14894, Apr. 7, 1982]

§ 193.20 Aluminum phosphide.

The food additive aluminum phosphide may be safely used in accordance with the following prescribed conditions:

(a) It is used to generate phosphine in the fumigation of processed foods.

(b) To assure safe use of the additive, it is used in compliance with label and labeling conforming to that registered with the U.S. Environmental Protection Agency. Labeling shall bear a warning to aerate the finished food for 48 hours before it is offered to the consumer. A further warning shall state that under no condition should the formulation containing aluminum phosphide be used so that it or its unreacted residues will come in contact with any processed food, except processed brewer's rice, malt, and corn grits stored in breweries for use in the manufacture of beer.

(c) Residues of phosphine in or on processed foods do not exceed 0.01 part per million.

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 44 FR 35210, June 19, 1979]

§ 193.25 4-Amino-6-(1,1-dimethylethyl)-3-methylthio)-1,2,4-triazin-5(4H)-one.

Tolerances are established for combined residues of the herbicide 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4*H*)-one and its triazinone metabolites in or on the following processed foods when present therein as a result of application of this herbicide to growing crops:

Food	Parts per million
Barley milled fractions (except flour)	3
Potatoes, processed (inc. potato chips)	3
Sugarcane molasses	2
Wheat milled fractions (except flour)	3

[44 FR 40283, July 10, 1979]

§ 193.30 Benomyl.

Tolerances of 50 parts per million are established for combined residues of the fungicide benomyl (methyl-1-(butylcarbamoyl)-2-benzimidazolecarbamate) and its metabolites containing the benzimidazole moiety (calculated as benomyl) in raisins and concentrated tomato products when present therein as a result of application of the fungicide to growing grapes and tomatoes.

(Sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2)))

[49 FR 29056, July 18, 1984]

§ 193.40 Captan.

A tolerance of 50 parts per million is established for residues of captan (*N*-trichloromethylmercapto-4-cyclohexene-1,2-dicarboximide) in or on washed raisins when present as a result of fungicidal treatment by preharvest application to grapes and postharvest application during the drying process.

§ 193.43 Carbofuran: tolerances for residues.

A tolerance is established for the combined residues of the insecticide carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranyl-*N*-methylcarbamate), its carbamate metabolite 2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benzofuranyl-*N*-methylcarbamate, and the phenolic metabolites 2,3-dihydro-2,2-dimethyl-7-benzofuranol, 2,3-dihydro-2,2-dimethyl-7-benzofuranol and 2,3-dihydro-2,2-dimethyl-3, 7-benzofurandiol in or on the following food commodity:

Commodity	Parts per million
Raisins (of which no more than 1.0 ppm is carbamate)	2.0

[46 FR 58487, Dec. 2, 1981]

§ 193.45 Carbon dioxide.

The food additive carbon dioxide may be safely used after harvest in modified atmospheres for stored product insect control on all processed agricultural commodities.

[46 FR 32866, June 25, 1981]

§ 193.50 Carbophenothion.

A tolerance of 20 parts per million is established for combined residues of the insecticide carbophenothion (*S*-[(*p*-cholorophenylthio) methyl]*O,O*-diethyl phosphorodithioate) and its cholinesterase-inhibiting metabolites in or on dried tea resulting from application of the insecticide to growing tea.

§ 193.60 Chlordimeform.

A tolerance of 15 parts per million is established for combined residues of the insecticide chlordimeform *N'*-(4-chloro-o-tolyl)-*N,N*-dimethylformamidine) and its metabolites containing the 4-chloro-*o*-toluidine moiety (calculated as the parent insecticide) in or on dried prunes from application of the insecticide to the growing raw agricultural commodity plums (fresh prunes).

§ 193.65 Combustion product gas.

The food additive combustion product gas may be safely used after harvest in modified atmospheres for stored product insect control on all processed agricultural commodities (except fresh meat) with the following prescribed conditions:

(a) The combustion product gas is produced by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment shall be provided with an absorption type filter capable of removing possible toxic impurities through which all gas used in the treatment of food shall pass and with suitable controls to insure that any combustion products failing to meet the specifications provided will be prevented from reaching the food being treated.

(b) The insecticide meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) It is used or intended for use to displace or remove oxygen in the storage of food, except fresh meat.

[46 FR 32866, June 25, 1981]

§ 193.70 (2-Chloroethyl) trimethylammonium chloride.

A tolerance of 6 parts per million is established for residues of the plant regulator (2-chloroethyl) trimethylammonium chloride in the sugarcane byproduct molasses, resulting from application of the plant regulator to the growing crop sugarcane. Such residues may be present therein only as a result of the application of the plant regulator to the growing sugarcane treated under an experimental permit, which expires October 4, 1975, and on which said sugarcane a temporary pesticide tolerance for the plant regulator expiring the same date has been established.

§ 193.80 1,1-Bis(p-chlorophenyl)-2,2,2-trichloroethanol.

A tolerance of 45 parts per million is established for residues of the insecticide 1,1-bis(*p*-chlorophenyl)-2,2,2-trichloroethanol in dried tea when present therein as a result of its application to the growing tea crop.

§ 193.83 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone.

Tolerances are established for the combined residues of the fungicide 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)-2-butanone and its metabolite beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol in or on the following food commodities:

Foods	Parts per million
Barley, milled fractions (except flour)	4.0
Wheat, milled fractions (except flour)	4.0

[48 FR 5901, Feb. 9, 1983]

§ 193.84 Chlorothalonil.

A regulation is established for the combined residues of the fungicide chlorothalonil (tetrachloroisophthalonitrile) and its metabolite (4-hydroxy-2,5,6-trichloroisophthalonitrile) in citrus oil at 10 parts per million (ppm) as a result of the preharvest application of chlorothalonil to growing citrus. This regulation expires December 31, 1983.

[47 FR 22950, May 26, 1982]

§ 193.85 Chlorpyrifos.

(a) Tolerances are established for the combined residues of the insecticide chlorpyrifos [*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] and its metabolite 3,5,6-trichloro-2-pyridinol resulting from application of the insecticide to growing crops as follows:

Foods	Parts per million
Citrus oil	25.0
Corn oil	3.0
Mint oil	10.0
Peanut oil	1.5

(b) The additive chlorpyrifos [*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] may be safely used in accordance with the following prescribed conditions.

(1) Application shall be limited solely to spot and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared or served. Contamination of food or food contact surfaces shall be avoided. Food must be removed or covered during treatment.

(2) Spray concentration for spot treatment shall be limited to a maximum of 0.5 percent of the active ingredient by weight. A course, low-pressure spray shall be used to avoid atomization or splashing of the spray.

(3) Paint-on application for spot treatment shall be limited to a maximum of 2 percent of the active ingredient by weight.

(4) Crack and crevice treatment shall be limited to a maximum of 2 percent of the active ingredient by weight. Equipment capable of delivering a pin-stream of insecticide shall be used.

(5) Application via adhesive strips shall contain a maximum of 10% by weight of the controlled-release product in food-handling establishments where food and food products are held, processed, prepared, or served. A maximum of 36 strips (or 5.15 grams of chlorpyrifos) is to be used per 100 square feet of floor space. The strips are not to be placed in exposed areas where direct contact with food, utensils, and food-contact surfaces would be likely to occur.

(6) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(c) A tolerance of 3.0 parts per million is established for the combined residues of the insecticide chlorpyrifos [*O,O*-diethyl *O*-[3,5,6-trichloro-2-pyridyl] phosphorothioate] and its metabolite 3,5,6-trichloro-2-pyridinol in or on the milling fractions of wheat [except flour] in accordance with an experimental use permit.

[47 FR 30478, July 14, 1982]

§ 193.87 Cypermethrin; tolerances for residues.

A regulation is established for residues of the insecticide cypermethrin [(±)alpha-cyano-(3-phenoxyphenyl) methyl(±)*cis, trans*-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] in cottonseed oil at 5 parts per million when present as a result of application of the insecticide to the growing cotton crop under an experimental use permit. This regulation expires March 5, 1984.

[47 FR 39479, Sept. 8, 1982]

§ 193.90 Copper.

A tolerance of 1 part per million is established in potable water for residues of copper resulting from the use of the algicides or herbicides basic copper carbonate (malachite), copper sulfate, copper monoethanolamine, and copper triethanolamine to control aquatic plants in reservoirs, lakes, ponds, irrigation ditches, and other potential sources of potable water.

[45 FR 53459, Aug. 12, 1980]

§ 193.97 Cyano(3-phenoxyphenyl)methyl 4-chloro-alpha-(1-methylethyl)benzeneacetate.

(a) A food additive tolerance of 0.05 ppm is established for residues of insecticide cyano(3-phenoxyphenyl)-methyl 4-chloro-alpha-(1-methylethyl)-benzeneacetate as follows:

(1) In or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments where food and food products are held, processed, or prepared.

(2) Application shall be limited to space treatment with a maximum of 0.5 fl. oz. of a 0.05 percent active ingredient solution per 1,000 cu. ft. of space, or as a contact spray applied as a coarse wet spray at a maximum of 1 gallon of a 0.2 percent active ingredient solution per 1,000 sq. ft. of surface. Food must be removed or covered during treatment. Spray should not be applied directly to surfaces or utensils that may come into contact with food. Food contact surfaces and equipment should be thoroughly cleaned before using.

(3) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

[49 FR 31666, Aug. 8, 1984]

§ 193.99 (±)Cyano(3-phenoxyphenyl)-meth-yl(+)-4-(difluoromethoxy)-alpha-(1-methylethyl)benzeneacetate.

A regulation is established permitting residues of the insecticide (±)cyano(3-phenoxy-phenyl)methyl-(+)-4-(difluoromethoxy)-alpha-(1-methylethyl)benzeneacetate in or on the following food commodity:

Commodity	Part per million (ppm)
Cottonseed Oil	0.2

[47 FR 616, Jan. 6, 1982; 47 FR 2986, Jan. 21, 1982]

§ 193.100 2,4-D.

Tolerances are established for residues of the herbicide 2,4-D (2,4-dichlorophenoxyacetic acid) as follows:

5 parts per million in sugarcane molasses resulting from application of the herbicide to sugarcane fields.

2 parts per million in the milled fractions (except flour) derived from barley, oats, rye, and wheat to be ingested as food or to be converted to food. Such residues may be present therein only as a result of application to the growing crop of the herbicides identified in 40 CFR 180.142.

0.1 part per million (negligible residue) in potable water. Such residues may be present therein only:

(a) As a result of the application of the dimethylamine salt of 2,4-D to irrigation ditch banks in the Western United States in programs of the Bureau of Reclamation; cooperating water user organizations; the Bureau of Sport Fisheries, U.S. Department of the Interior; Agricultural Research Service, U.S. Department of Agriculture; and the Corps of Engineers, U.S. Department of Defense.

(b) As a result of the application of the dimethylamine salt of 2,4-D for water hyacinth control in ponds, lakes, reservoirs, marshes, bayous, drainage ditches, canals, rivers and streams that are quiescent or slow moving in programs of the Corps of Engineers or other Federal, State, or local public agencies.

(c) As a result of application of the dimethylamine salt of 2,4-D and the butoxyethamol ester of 2,4-D to Lake Seminole in Florida and Georgia, Robert S. Kerr Reservoir in Oklahoma, Fort Cobb Reservoir in Oklahoma, and Banks Lake in Washington under an experimental use program which expires on February 28, 1982. This program is to be conducted by the Water and Power Resources Service, U.S. Department of Interior and the

Corps of Engineers, U.S. Army. Residues remaining in potable water after February 28, 1982 will not be considered actionable if the pesticide is legally applied during the term and in accordance with provisions of the experimental permit and food additive tolerance.

(d) As a result of application of its dimethylamine salt or its butoxyethanol ester for Eurasian watermilfoil control in programs conducted by the Tennessee Valley Authority in dams and reservoirs of the TVA system.

[40 FR 58288, Dec. 16, 1975, as amended at 41 FR 11483, Mar. 19, 1976; 41 FR 23379, June 10, 1976. Redesignated at 41 FR 26568, June 28, 1976, and amended at 45 FR 47143, July 14, 1980]

§ 193.105 Dalapon.

A tolerance of 0.2 part per million is established for residues of the herbicide dalapon (2,2-dichloropropionic acid) in potable water when present therein as a result of the application of dalapon sodium-magnesium salt mixtures to irrigation ditch banks in the western United States.

[43 FR 22345, May 25, 1978]

§ 193.130 Dialifor.

A tolerance of 2 parts per million is established for combined residues of the insecticide dialifor (*S*-(2-chloro-1-phthalimidoethyl) *O,O*-diethyl phosphorodithioate) and its oxygen analog *S*-(2-chloro-1-phthalimidoethyl *O,O*-diethyl phosphorothioate) in or on raisins from application of the insecticide to the growing raw agricultural commodity grapes.

§ 193.135 Diatomaceous earth.

The food additive diatomaceous earth may be safely used in accordance with the following conditions. Application shall be limited solely to spot and/or crack and crevice treatments in food processing and food storage areas in accordance with the prescribed conditions:

(a) It is used or intended for use for control of insects in food processing and food storage areas: *Provided*, That the food is removed or covered prior to such use.

(b) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

[46 FR 55511, Nov. 10, 1981]

§ 193.137 3-(3,5-Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione.

Tolerances are established for the combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the following food commodities:

Foods	Parts per million
Prunes	75

[51 FR 11437, Apr. 3, 1986]

§ 193.140 2,2-Dichlorovinyl dimethyl phospate.

The food additive 2,2-dichlorovinyl dimethyl phosphate may be present as a residue, from application as an insecticide on packaged or bagged nonperishable processed food (see: 170.3(j)), in an amount in such food not in excess of 0.5 part per million (ppm); or from application as an insecticide to growing fig trees, in an amount in dried figs not in excess of 0.5 ppm. To assure safe use of the insecticide, its label and labeling shall conform to the label and labeling registered by the U.S. Environmental Protection Agency and the usage employed shall conform with such label or labeling.

[47 FR 55214, Dec. 8, 1982; 47 FR 56845, Dec. 21, 1982]

§ 193.142 0,0-Diethyl 0-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate.

The food additive *0,0*-Diethyl *0*-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate may be safely used in accordance with the following prescribed conditions:

(a) Application shall be limited solely to spot and/or crack and crevice treatment in food handling establishments, including food service, manufacturing, and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries where food and food products are held, processed, and served.

(1) Spray and dust concentrations shall be limited to a maximum of 1 percent and 2 percent, respectively, of active ingredient by weight. The spray concentration limit of 1 percent shall include, but not be limited to, encapsulated formulations of the additive utilizing the encapsulating polymer formed from the reaction of sebacoyl chloride, polymethylene polyphenylisocyanate, ethylenediamine and/or diethylenetriamine.

(2) Application to areas, surfaces, or utensils contacted by food, contamination of food and food contact surfaces, and the introduction of spray or dust into the air is to be avoided.

(3) For spot treatment, a coarse, low pressure spray shall be used. Application is limited to floor surfaces only and to 20 percent of the surface area. Any individual spot treatment shall not exceed 2 square feet.

(4) For crack and crevice treatment, equipment capable of delivering dust or a pin stream of spray directly into the cracks and crevices shall be used.

(b) To assure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

[45 FR 12700, Feb. 18, 1981, as amended at 47 FR 25952, June 16, 1982]

§ 193.145 3,5-Dimethyl-4-(methylthio) phenyl methylcarbamate.

(a) A tolerance of 25 parts per million is established for combined residues of the bird repellant 3,5 - dimethyl - 4 - (methylthio)phenyl methylcarbamate and its cholinesterase-inhibiting metabolites in or on raisins resulting from application of the pesticide to the growing raw agricultural commodity grapes in accordance with the provisions of an experimental use permit that expires December 31, 1980.

(b) Residues in or on raisins not in excess of 25 parts per million resulting from the use described in paragraph (a) of this section remaining after expiration of the experimental use program will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and food additive tolerance.

(c) Mobay Chemical Corp., Chemagro Chemical Division, shall immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

[43 FR 29558, July 10, 1978, as amended at 44 FR 38842, July 3, 1979; 45 FR 18374, Mar. 21, 1980]

§ 193.150 *O,O*-Dimethyl S-[4-oxo-1,2,3-benzotriazin-3 (4H)-ylmethyl] phosphorodithioate.

A tolerance of 1 part per million is established for residues of the insecticide *O,O*-dimethyl *S*-[4-oxo-1,2,3-benzotriazin-3(4*H*)-ylmethyl] phosphorodithioate in soybean oil resulting from application of the insecticide to the raw agricultural commodity soybeans.

§ 193.151 Dimethyl phosphate of 3-hydroxy-*N*-methyl-cis-crotonamide.

A tolerance of 2 parts per million is established for residues of the insecticide dimethyl phosphate of 3-hydroxy-*N*-methyl-cis-crotonamide in concentrated tomato products when present therein as a result of application of the insecticide to growing tomatoes.

(Sec. 409(c) (1) & (4), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c) (1) & (4)), transferred to the Administrator EPA in Reorganization Plan No. 3 of 1970 (35 FR 15623))

[40 FR 18168, Apr. 25, 1975. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.152 2,2-dimethyl-1,3-benzodioxol-4-ol methylcarbamate.

(a) The insecticide 2,2-dimethyl-1,3-benzodioxol-4-ol methylcarbamate may be safely used in spot and/or crack and crevice treatments in food handling establishments, including food service, manufacturing and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries.

(b) To ensure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label and labeling.

(c) A tolerances of 0.1 part per million is established for the combined residues of the insecticide 2,2-dimethyl-1,3-benzodioxol-4-ol methylcarbamate and its metabolites 2,2-dimethyl-1,3-benzodioxol-4-ol and *N*-hydroxymethyl bendiocarb in corn oil intended for food use resulting from the application of the insecticide in the growing of corn. Such residues may be present therein only as a result of the application of the insecticide to growing corn under an experimental use permit. This regulation expires January 27, 1983.

(Sec. 409(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(1) transferred to the Administrator EPA in Reorganization Plan No. 3 (35 FR 15623))

[40 FR 45163, Oct. 1, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 47 FR 14895, Apr. 7, 1982]

§ 193.156 O,O-Dimethyl O-(4-nitro-m-tolyl) phosphorothioate.

(a) A tolerance of 30 parts per million, of which no more than 15 parts per million is *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphorothioate or *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphate, is established for combined residues of the insecticide *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphorothioate and its metabolites *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphate and 3-methyl-4-nitrophenol in wheat gluten resulting from postharvest application of the insecticide to stored wheat in Australia.

(b) A food additive regulation is established for the combined residues of the insecticide *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphorothioate and its metabolite, *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphate in food items at 0.5 part per million resulting from the application of solutions containing a maximum concentration of 1.0 percent of the insecticide in food handling establishments. Application shall be limited solely to spot or crack and crevice treatments. For crack and crevice treatments, equipment capable of delivering a pin-stream of insecticide shall be used. For spot treatments, a coarse, low pressure spray shall be used to avoid atomization or splashing of the spray. Contamination of food or food-contact surfaces shall be avoided. Such residues may be present therein only as a result of application with the provisions of an experimental use permit. This regulation expires June 17, 1983.

(c) Residues in food items not in excess of 0.5 part per million resulting from the use as described in paragraph (b) of this section remaining after expiration of the experimental use program will not be considered actionable if the insecticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and food additive regulation.

(d) Stauffer Chemical Company will immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm will also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

[44 FR 40282, July 10, 1979, as amended at 47 FR 28367, June 30, 1982]

§ 193.160 Diquat.

(a) A tolerance of 0.01 ppm is established for residues of the herbicide diquat (6,7-dihydrodipyrido (1,2-a:2',1'-c) pyrazidiinium) derived from application of the dibromide salt in potable water resulting from the application of the pesticide for control of aquatic weeds in ponds, lakes, reservoirs, marshes, bayous, drainage ditches, canals, streams, and rivers which are slow-moving or quiescent in programs of the Corps of Engineers or other Federal or State public agencies. These agencies or contractors or licensees under their direct control will make certain that the treated water will not be used for animal consumption, swimming, spraying, domestic purposes, or for irrigation for 14 days post-treatment or until approved analysis shows that the water does not contain more than 0.01 ppm of diquat (calculated as the cation) and that no treatment will be made where commercial processing of fish resulting in the production of fish protein concentrate or fish meal is practiced.

(b) A tolerance of 0.01 ppm is established for residues of the herbicide diquat (6,7-dihydrodipyrido (1,2-a:2′,1′-c) pyrazidiinium) (calculated as the cation) derived from application of the dibromide salt in potable water resulting from the application of the pesticide in ponds, lakes, and drainage ditches where there is little or no outflow of water and which are totally under control of the user. The applicator will make certain that treated water will not be used for animal consumption, swimming, spraying, irrigation, or domestic purposes for 14 days post-treatment. For the purposes of this paragraph only (§ 193.160(b)) these applications of diquat are not to be used in aquatic sites in Florida.

(c) A food additive regulation of 0.5 part per million is established for residues of diquat in processed potatoes (includes potato chips).

[46 FR 30339, June 8, 1981, and 47 FR 8007, Feb. 24, 1982]

§ 193.170 Endosulfan.

A tolerance of 24 parts per million is established for combined residues of the insecticide endosulfan (6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide) and its metabolite endosulfan sulfate (6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide) in or on dried tea (reflecting less than 0.1 part per million residues in beverage tea) resulting from application of the insecticide to growing tea.

§ 193.180 Endothall.

An interim tolerance of 0.2 part per million is established for residues of the herbicide endothall (7-oxabicyclo[2.2.1] heptane-2,3-dicarboxylic acid) in potable water from use of its potassium, sodium, di-*N*,N-dimethylalkylamine, and mono-*N*-N-dimethylalkylamine salts as algicides or herbicides to control aquatic plants in canals, lakes, ponds, and other potential sources of potable water.

§ 193.186 Ethephon.

(a) A food additive regulation is established permitting residues of the plant growth regulator ethephon [(2-chloroethyl) phosphonic acid] in or on the following food commodities:

Foods	Parts per million
Barley, milling fractions, except flour	5.0
Wheat, milling fractions, except flour	5.0

(b) A food additive regulation is established for the plant growth regulator ethephon [(2-chloroethyl)-phosphonic acid] in or on the following food commodities resulting from application of ethephon to growing crops in accordance with an experimental use program.

Foods	Parts per million	Company	Expiration date
Sugarcane, molasses	7.0	Union Carbide	July 14, 1988

(c) The following conditions for the regulation in paragraph (b) of this section shall be met.

(1) Residues in the food in excess of the established tolerance resulting from the use described in paragraph (b) of this section remaining after ex-

piration of the experimental use program will not be considered to be actionable if the plant growth regulator is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and the food additive regulation.

(2) The Company concerned shall immediately notify the Environmental Protection Agency of any findings for the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

[47 FR 20763, June 23, 1982, as amended at 50 FR 14097, Apr. 10, 1985; 51 FR 31325, Sept. 3, 1986]

§ 193.190 Ethion.

Tolerances for residues of the insecticide ethion (*O,O,O′,O′*-tetraethyl *S,S′*-methylene bisphosphorodithioate), including its oxygen analog (*S*-[[(diethoxyphosphinothioyl) thio]methyl]*O, O*-diethyl phosphorothioate), when present as a result of its application to growing agricultural commodities are established as follows:

10 parts per million in dried tea.
4 parts per million in raisins.

§ 193.200 Ethylene oxide.

Ethylene oxide may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices and other processed natural seasoning materials, except mixtures to which salt has been added, in accordance with the following prescribed conditions:

(a) Ethylene oxide, either alone or admixed with carbon dioxide or dichlorodifluoromethane, shall be used in amounts not to exceed that required to accomplish the intended technical effects. If used with dichlorodifluoromethane, the dichlorodifluoromethane shall conform with the requirements prescribed by § 173.355 of this chapter.

(b) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label or labeling.

(c) Residues of ethylene oxide in ground spices from both postharvest application to the raw agricultural commodity whole spices and application to the ground spices shall not exceed the established tolerance of 50 parts per million for residues in whole spices in 40 CFR 180.151.

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 50 FR 2958, Jan. 23, 1985]

§ 193.210 Ethyl formate.

The food additive ethyl formate may be safely used in or on specified dried fruits in accordance with the following prescribed conditions:

(a) It is used or intended for use in or on raisins and dried Zante currants as a bulk and package fumigant.

(b) It is used in accordance with directions registered with the U.S. Environmental Protection Agency, and so used that the total formic acid present free and combined, in the finished product shall not exceed 250 parts per million.

(c) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency.

§ 193.212 *O*-Ethyl *O*-[4-(methylthio) phenyl] *S*-propyl phosphorodithioate.

A tolerance of 1 part per million is established for residues of the insecticide *O*-ethyl *O*-[4-(methylthio)-phenyl] *S*-propyl phosphorodithioate and its cholinesterase-inhibiting metabolites in cottonseed oil resulting from application of the pesticide to growing cotton.

[43 FR 32130, July 25, 1978]

§ 193.215 Fenthion.

The food additive fenthion (*O,O*-dimethyl (*O*-3-methyl-4-(methylthio) phenyl phosphorothioate) may be safely used in accordance with the following prescribed conditions:

(a) It is used only for insect control in spot, crack, and crevice treatment in food handling establishments in accordance with the terms of the experimental use permit which expires February 27, 1977.

(b) Residues in food resulting from the use described in paragraph (a) of this section shall not exceed 1 part per million. Residues in foods not in excess of this tolerance remaining after expiration of the experimental use program will not be considered actionable if the insecticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and food additive tolerance.

(c) Chemagro Agricultural Division of Mobay Chemical Co., will immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The company will also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

(d) To assure safe use of the additive, its label and labeling shall conform to that approved by the U.S. Environmental Protection Agency in conjunction with the issuance of the experimental use permit.

[41 FR 8976, Mar. 2, 1976. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.219 Fluridone.

(a) [Reserved]

(b) A tolerance of 0.01 part per million is established for residues of the herbicide fluridone [1-methyl-3-phenyl-5-(3)-trifluoromethyl)-phenyl)-4(1*H*)-pyridinone] in potable water. Such residues may be present therein only as a result of application of the herbicide fluridone to lakes and ponds under an experimental use program which expires June 1, 1985.

This program is to be conducted by Elanco Products Company. Residues remaining in potable water after June 1, 1985, will not be considered actionable if the pesticide is legally applied during the term and in accordance with the provisions of the experimental use permit and the food additive tolerance.

[48 FR 23386, May 25, 1983, as amended at 49 FR 26572, June 28, 1984]

§ 193.220 Formetanate hydrochloride.

A tolerance of 8 parts per million is established for residues of the insecticide formetanate hydrochloride (*m*-[(dimethylamino) methylene amino] phenyl methyl-carbamate hydrochloride) in dried prunes when present therein as a result of the application of the insecticide to growing plums (fresh prunes).

§ 193.225 Fumigants for grain-mill machinery.

Fumigants may be safely used in or on grain-mill machinery in accordance with the following prescribed conditions:

(a) The fumigants consist of one or more of the following: carbon disulfide, carbon tetrachloride, ethylene dichloride, methyl bromide.

(b) To assure safe use of the fumigant, its label and labeling shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

(c) Residues of inorganic bromides (calculated as Br) in milled fractions derived from cereal grain from all fumigation sources, including fumigation of grain-mill machinery, shall not exceed 125 parts per million.

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 49 FR 44459, Nov. 7, 1984]

§ 193.230 Fumigants for processed grains used in production of fermented malt beverages.

Fumigants for processed grain may be safely used, in accordance with the following conditions.

(a) They consist of one of the following:

(1) Carbon tetrachloride with either carbon disulfide or ethylene dichloride, with or without pentane.

(2) Methyl bromide. Total residues of inorganic bromides (calculated as Br) from the use of methyl bromide and any previous fumigations with methyl bromide shall not exceed 125 parts per million.

(b) They are used to fumigate corn grits and cracked rice used in the production of fermented malt beverages.

(c) To assure safe use of the fumigant, its label and labeling shall conform to the label and labeling registered by the U.S. Environmental Protection Agency, and the usage employed should conform with such label or labeling.

(d) The total residue of inorganic bromides in fermented malt beverages, resulting from the use of corn grits and cracked rice fumigated with the fumigant described in paragraph (a)(2) of this section plus additional residues of inorganic bromides that may be present from uses in accordance with other regulations in this chapter promulgated under section 408 and/or 409 of the Act, does not exceed 25 parts per million bromide (calculated as Br).

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 49 FR 44459, Nov. 7, 1984]

§ 193.235 Glyphosate.

(a) Tolerances are established for the combined residues of the herbicide glyphosate and the metabolites as indicated when present therein as a result of the herbicide application to the growing crops.

(1) Glyphosate [*N*-(phosphonomethyl)glycine] and its metabolite aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate for herbicidal purposes and/or the sodium sesqui salt for plant growth regulator purposes.

Foods	Parts per million
Molasses, sugarcane	30.0

(2) Glyphosate [*N*-(phosphonomethyl)glycine] and its metabolite aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate for herbicidal purposes.

Foods	Parts per million
Oil, palm	0.1
Olives, imported	0.1
Tea, dried	1.0
Tea, instant	4.0

(b) A tolerance of 0.1 ppm is established for the combined residues of the herbicide glyphosate [*N*-(phosphonomethyl)glycine] and its metabolite aminomethylphosphonic acid in potable water resulting from the application of the herbicide in accordance with the provisions of an experimental use permit that expires January 1, 1983.

(1) Residues in potable water not in excess of 0.1 ppm, resulting from the use described in paragraph (b) of this section remaining after expiration of the experimental program will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and the food additive regulation.

(2) Monsanto Company shall immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance and, on request, make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

[48 FR 56577, Dec. 22, 1983]

§ 193.236 Hexakis.

A regulation is established permitting the combined residues of the insecticide hexakis (2-methyl-2-phenylpropyl) distannoxane and its organotin metabolites calculated as hexakis (2-methyl-2-phenylpropyl) distannoxane in or on the following food items:

Food	Parts per million
Prunes, dried	20.0
Raisins	20

[47 FR 21532, May 19, 1982, as amended at 48 FR 37204, Aug. 17, 1983; 48 FR 39058, Aug. 29, 1983]

§ 193.240 Hydrogen cyanide.

The food additive hydrogen cyanide may be present as a residue in certain processed foods in accordance with the following prescribed conditions:

(a) The food additive is present as a result of its use as a fumigant.

(b) The residues of hydrogen cyanide shall not exceed the following levels:

(1) 125 parts per million in cereal flours.

(2) 90 parts per million in cereals that are cooked before being eaten.

(3) 50 parts per million in uncooked ham, bacon, and sausage.

(4) 200 parts per million in cocoa.

(c) Where tolerances are established under both sections 408 and 409 of the Act on the raw agricultural commodity and on the processed food, respectively, the total residues of hydrogen cyanide in or on the processed food shall not be greater than that designated in paragraph (b) of this section.

(d) To assure safe use of the additive, the label and labeling of the pesticide formulation containing the food additive shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

§ 193.250 Inorganic bromide.

The food additive inorganic bromide may be present as a residue in certain processed foods in accordance with the following conditions:

(a) When the food additive is present as a result of fumigation of the processed food with methyl bromide or from such fumigation in addition to the authorized use of methyl bromide or the nematocide 1,2-dibromo-3-chloropropane on the source raw agricultural commodity, as provided for in 40 CFR Part 180, the total residues of inorganic bromides (calculated as Br) shall not exceed the following levels:

400 parts per million in or on dried eggs and processed herbs and spices.
325 parts per million in or on parmesan cheese and roquefort cheese.
250 parts per million in or on concentrated tomato products and dried figs.
125 parts per million in or on processed foods other than those listed above.

(b) [Reserved]

(c) When the food additive is present in fermented malt beverages in accordance with §§ 193.230 and/or 172.730(a)(2) of this chapter, the amount shall not exceed 25 parts per million (calculated as Br).

(d)-(v) [Reserved]

(w) Where tolerances are established under sections 408 and 409 of the act on both the raw agricultural commodities and processed foods made therefrom the total residues of inorganic bromides in or on the processed food shall not be greater than those designated in paragraphs (a) and (b) of this section, unless a higher level is established elsewhere in 40 CFR 180.151 or in this part.

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 49 FR 17149, Apr. 23, 1984; 50 FR 2958, Jan. 23, 1985; 50 FR 3755, Jan. 28, 1985]

§ 193.251 Bromide ion and residual bromine.

The food additives, bromide ion and residual bromine, may be present in potable water in accordance with the following conditions:

(a) The food additives are present as a result of treating water aboard ships with a polybrominated ion-exchange resin (as a source of bromine) under the supervision of trained personnel.

(b) Residual bromine levels are controlled to not exceed 1.0 part per million (ppm) in the final treated water. Control is effected using calibrated recirculating or proportioning bromine feeder equipment and periodic checks of residual bromine using a bromine test kit. To assure safe use of the additives, the label and labeling of the disinfectant formulation containing the food additives shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

(c) No tolerance is established for bromide ion levels.

[41 FR 17893, Apr. 29, 1976. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.253 Iprodione.

Tolerances are established for the combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methyl-ethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide in or on the following food commodity:

Foods	Parts per million
Raisins	300

[50 FR 4208, Jan. 30, 1985]

§ 193.255 Magnesium phosphide.

The food additive magnesium phosphide may be safely used in accordance with the following prescribed conditions:

(a) It is used to generate phosphine in the fumigation of processed foods.

(b) To assure safe use of the additive, it is used in compliance with the label and labeling conforming to that registered with the U.S. Environmental Protection Agency. The labeling shall bear a warning to aerate the finished food for 48 hours before it is offered to the consumer. A further warning shall state that under no condition should the formulation containing magnesium phosphide be used so that it or its unreacted residues will come in contact with any processed food.

(c) Residues of phosphine in or on processed foods do not exceed 0.01 part per million.

[43 FR 56040, Nov. 30, 1978]

§ 193.260 Malathion.

Malathion may be safely used in accordance with the following conditions:

(a)(1) It is incorporated into paper trays in amounts not exceeding 100 milligrams per square foot.

(2) Treated paper trays are intended for use only in the drying of grapes (raisins).

(3) Total residues of malathion resulting from drying of grapes on treated trays and from application to grapes before harvest shall not exceed 12 parts per million on processed ready-to-eat raisins.

(b) Residues of malathion in refined safflower oil from application to the growing safflower plant shall not exceed 0.6 part per million.

§ 193.270 Maleic hydrazide.

A food additive known as maleic hydrazide (1,2-dihydro-3,6-pyridazinedione) may be present in potato chips when used in accordance with the following conditions:

(a) The food additive is present as a result of the application of a pesticide formulation containing maleic hydrazide to the growing potato plant in accordance with directions registered by the U.S. Environmental Protection Agency.

(b) The label of the pesticide formulation containing the food additive conforms to labeling registered by the U.S. Environmental Protection Agency.

(c) The food additive is present in an amount not to exceed 160 parts per million by weight of the finished food.

§ 193.275 N-(Mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate) and its oxygen analog.

Tolerances are established for residues of the insecticide *N*-(mercaptomethyl)phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) and its oxygen analog *N*-(mercaptomethyl)phthalimide *S*-(*O,O*-dimethyl phosphorothioate) in the following processed food when present therein as a result of application of the insecticide to growing cotton.

Food	Parts per million
Cottonseed oil	0.2

[45 FR 8979, Feb. 11, 1980]

§ 193.277 Metalaxyl.

(a) A regulation is established permitting the combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methyl)-*N*-methoxyacetyl)-alanine methylester, each expressed as metalaxyl, in or on the following food commodities:

Foods	Parts per million
Citrus, oil	7.0
Potatoes, processed (including potato chips)	4.0
Tomatoes, processed	3.0

(b) *Indirect or inadvertent tolerances.* Tolerances are established for indirect or inadvertent residues of metalaxyl in the food commodities when present therein as a result of the application of metalaxyl to growing crops listed in 40 CFR 180.408(a) and other non-food crops as listed below:

Foods	Parts per million
Wheat, milling fractions	1.0

(c) A regulation is established permitting the combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methyl)-*N*-methoxyacetyl)-alanine methylester, each expressed as metalaxyl, in processed tomato products at 3.0 parts per million resulting from application of metalaxyl to growing tomatoes under an experimental use program. This regulation expires January 1, 1984.

[48 FR 3587, Jan. 26, 1983, as amended at 50 FR 49688, Dec. 4, 1985]

§ 193.280 Metaldehyde.

The food additive metaldehyde may be safely used as a preharvest spray or dust on strawberries to control slugs and snails, in accordance with the following prescribed conditions:

(a) The food additive is applied as a preharvest spray or dust on growing strawberries at a rate of not more than 1 pound per acre, calculated as metaldehyde, and applied not later than 14 days before first picking.

(b) A tolerance of zero is established for residues of metaldehyde on strawberries.

(c) To insure safe usage of the additive:

(1) The label of any market package of the additive shall bear, in addition to other information required by the act, the name of the additive.

(2) The label of any prepared mix or concentrate shall indicate the percentage by weight of the additive.

(3) The label shall bear adequate directions for use, in conformance with paragraph (a) of this section and may indicate that in the event the metaldehyde is removed by rain an additional application may be made provided such application is made not less than 14 days before first picking.

§ 193.284 Methanearsonic acid.

(a) A tolerance of 3 parts per million is established for residues of the herbicide methanearsonic acid (expressed as As_2O_3) in sugarcane molasses, sugar, and syrup resulting from application of its monosodium salt to growing sugarcane in accordance with the provisions of an experimental use permit that expires July 22, 1977.

(b) Residues not in excess of 3 parts per million in sugarcane molasses, sugar, and syrup resulting from the use described in paragraph (a) of this section remaining after expiration of the experimental program will not be considered to be actionable if the pesticide is legally applied during the term of and in accordance with the provision of the experimental use permit and food additive tolerance.

(c) Ansul Co. shall immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration. Sugarcane bagasse obtained from sugarcane treated under this experimental program shall not be used for feed purposes.

[41 FR 31530, July 29, 1976]

§ 193.285 Methoprene.

(a) The insect growth regulator methoprene (isopropyl (E,E-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate)) is exempt from the requirement of a tolerance in potable water when used on pastures, rice fields, marshlands, and other noncrop areas to control floodwater mosquitoes.

(b)(1) A tolerance of 10 parts per million is established for the insect growth regulator methoprene in or on raisins, wheat flour, macaroni (wheat), rice cereal, rye cereal, barley cereal, wheat cereal, corn cereal, corn meal, grits, hominy, oat cereal, spices, dry dog food, dried apples, dried apricots, dried peaches, and dried prunes resulting from applications of methoprene in accordance with the provisions of an experimental use permit that expires September 21, 1986.

(2) The total amount of the active ingredient to be used shall not exceed the quantity authorized by the experimental use permit.

(3) The Company concerned shall immediately notify the Environmental Protection Agency of any findings for the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 49 FR 48271, Dec. 12, 1984]

§ 193.290 1-Methoxycarbonyl-1-propen-2-yl dimethylphosphate and its beta isomer.

A tolerance of 4 parts per million is established for residues of the insecticide 1-methoxycarbonyl-1-propen-2-yl dimethylphosphate and its beta isomer in dehydrated parsley when present as a result of application of the insecticide to the growing crop.

§ 193.300 Methyl chloride.

The food additive methyl chloride may be safely used in accordance with the following prescribed conditions:

(a) It is used or intended for use as a propellant in pesticide formulations in an amount not to exceed 30 percent of the finished formulation.

(b) It is used or intended for use in food storage and processing areas whereby spray applications do not contact fatty foods.

(c) To assure safe use of the additive, the label and labeling of the pesticide formulation containing the food additive shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

§ 193.301 2-(1-Methylethoxy)phenol methylcarbamate.

Tolerances of 0.2 part per million are hereby established for residues of the insecticide 2-(1-methylethoxy) phenol methylcarbamate in food commodities exposed to the insecticide during treatment of food handling establishments. Such residues may be present therein only as a result of the use of the insecticide in an experimental program which expires May 8, 1977. Residues remaining in or on the food commodities after expiration of these tolerances will not be considered actionable if the pesticide is legally applied during the term and in accordance with provisions of the temporary permit/food additive tolerances.

[41 FR 47231, Oct. 28, 1976; 41 FR 51009, Nov. 19, 1976]

§ 193.310 Methyl formate.

The food additive methyl formate may be safely used in or on specified dried fruits in accordance with the following prescribed conditions:

(a) It is used or intended for use in or on raisins and dried Zante currants as a bulk and package fumigant.

(b) It is used in accordance with directions registered with the U.S. Environmental Protection Agency, and so used that the total formic acid present, free and combined in the finished product shall not exceed 250 parts per million.

(c) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency.

§ 193.320 *N*-Octylbicycloheptene dicarboximide.

The food additive *N*-octylbicycloheptene dicarboximide may be safely used in accordance with the following prescribed conditions:

(a) It is used in combination with piperonyl butoxide and pyrethrins for insect control in food-processing and food-storage areas, provided that the food is removed or covered prior to such use.

(b) Residues in food resulting from the use described in paragraph (a) of this section shall not exceed 10 parts per million of *N*-octylbicycloheptene dicarboximide, 10 parts per million of piperonyl butoxide, and 1 part per million of pyrethrins.

(c) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label and labeling.

§ 193.323 Nitrogen.

The food additive nitrogen may be safely used after harvest in modified atmospheres for stored product insect control on all processed agricultural commodities.

[46 FR 32866, June 25, 1981]

§ 193.324 Norflurazon.

A regulation is established for the combined residues of the herbicide norflurazon (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3(2*H*)-pyridazinone) and its desmethyl metabolite (4-chloro-5-amino-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3(2*H*)-pyridazinone) in dried hops at 3.0 parts per million when present therein as a result of its application to the growing crop.

[47 FR 14896, Apr. 7, 1982]

§ 193.325 Oxyfluorfen.

A regulation is established permitting the combined residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] and its metabolities containing the diphenyl ether linkage in the following processed food when present therein as a result of application of the herbicide to growing crops:

Food commodity	Part per million (ppm)
Cottonseed oil	0.25
Mint oil (peppermint and spearmint)	0.25
Soybean oil	0.25

[47 FR 1375, Jan. 13, 1982]

§ 193.330 Paraformaldehyde.

The food additive paraformaldehyde may be safely used in accordance with the following prescribed conditions.

(a) It is used to control microbial or fungal growth in maple tree tapholes

(b) It is so used that the maple sirup produced from the sap of treated maple trees does not contain in excess of 2 parts per million of formaldehyde.

§ 193.331 Paraquat.

A tolerance of 0.2 part per million is established for residues of the defoliant, desiccant, and herbicide paraquat (1,1′-dimethyl-4,4′-bipyridinium ion) derived from the application of either the bis (methyl sulfate) or dichloride salt (both calculated as the cation) in or on dried hops resulting from application of the pesticide to growing hops.

[40 FR 43720, Sept. 23, 1975. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.340 Phosalone.

Tolerances are established for residues of the insecticide phosalone (*S*-(6-chloro-3-(mercaptomethyl)-2-benzoxazolinone) *O,O*-diethyl phosphorodithioate) in or on the following processed foods when present therein as a result of application of the insecticide to the growing crops:

40 parts per million in or on dried prunes.
20 parts per million in or on raisins.
8 parts per million in or on dried tea.

§ 193.350 Picloram.

Tolerances are established for residues of picloram [4-amino-3,5,6-trichloropicolinic acid] resulting from the application of the pesticide to growing crops in the following:

Feed	Parts per million
Barley, milled fractions (exc flour)	3
Oats, milled fractions (exc flour)	3
Wheat, milled fractions (exc flour)	3

[41 FR 19211, May 11, 1976. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.360 Piperonyl butoxide.

The food additive piperonyl butoxide may be safely used in accordance with the following prescribed conditions:

(a) It is used or intended for use in combination with pyrethrins for control of insects:

(1) In cereal grain mills and in storage areas for milled cereal grain products, whereby the amount of piperonyl butoxide is at least equal to but not more than 10 times the amount of pyrethrins in the formulation.

(2) On the outer ply of multiwall paper bags of 50 pounds or more capacity in amounts not exceeding 60 milligrams per square foot, whereby the amount of piperonyl butoxide is equal to 10 times the amount of pyrethrins in the formulation. Such treated bags are to be used only for dried foods.

(3) On cotton bags of 50 pounds or more capacity in amounts not exceeding 55 milligrams per square foot of cloth, whereby the amount of piperonyl butoxide is equal to 10 times the amount of pyrethrins in the formulation. Such treated bags are constructed with waxed paper liners and are to be used only for dried foods that contain 4 percent fat or less.

(4) In two-ply bags consisting of cellophane/polyolefin sheets bound together by an adhesive layer when it is incorporated in the adhesive. The treated sheets shall contain not more than 50 milligrams of piperonyl butoxide per square foot (538 milligrams per square meter). Such treated bags are to be used only for packaging prunes, raisins, and other dried fruits and are to have a maximum ratio of 3.12 milligrams of piperonyl butoxide per ounce of fruit (0.10 milligram of piperonyl butoxide per gram of product).

(5) In food processing and food storage areas: *Provided*, That the food is removed or covered prior to such use.

(b) It is used or intended for use in combination with pyrethrins and *N*-octylbicycloheptene dicarboximide for insect control in accordance with § 178.3730.

(c) A tolerance of 10 parts per million is established for residues of piperonyl butoxide in or on:

(1) Milled fractions derived from cereal grains when present therein as a result of its use in cereal grain mills and in storage areas for milled cereal grain products.

(2) Dried foods when present as a result of migration from its use on the outer ply of multiwall paper bags of 50 pounds or more capacity.

(3) Foods treated in accordance with § 178.3730.

(4) Dried foods that contain 4 percent fat, or less, when present as a result of migration from its use on the cloth of cotton bags of 50 pounds or more capacity constructed with waxed paper liners.

(5) Foods treated in accordance with paragraph (a)(4) and (5) of this section.

(d) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(e) Where tolerances are established under sections 408 and 409 of the Act on both raw agricultural commodities and processed foods made therefrom, the total residues of piperonyl butoxide in or on the processed food shall not be greater than that permitted by the larger of the two tolerances.

[40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 50 FR 2958, Jan. 23, 1985.

§ 193.370 Propargite.

Tolerances are established for residues of the insecticide propargite (2-(*p-tert*-butylphenoxy)cyclohexyl 2-propynyl sulfite) in or on the following processed foods when present therein as a result of the application of this insecticide to growing crops:

Feed	Parts per million
Figs, dried	9
Hops, dried	30
Raisins	25
Tea, dried	10

[44 FR 38841, July 3, 1979]

§ 193.375 Propetamphos.

A tolerance of 0.1 part per million is established for residues of the insecticide propetamphos ([(e)-]-methylethyl 3-[[(ethylamino) methoxyphosphinothioyl]oxy]-2-butenoate]) in food commodities exposed to the insecticide during treatment of food-handling establishments.

(a) Direct application shall be limited solely to spot and/or crack and crevice treatment in food-handling establishments where food and food products are held, processed, prepared, or served. Spray and dust concentrations shall be limited to a maximum of 1 percent active ingredient. For crack and crevice treatment, equipment capable of delivering a dust or a pin-stream of spray directly into cracks and crevices shall be used. For spot treatment, a coarse, low-pressure spray shall be used to avoid contamination of food or food-contact surfaces.

(b) To ensure safe use of the insecticide, its label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

[48 FR 52902, Nov. 23, 1983]

§ 193.380 Propylene oxide.

The food additive propylene oxide may be safely used in or on foods in accordance with the following prescribed conditions:

(a) It is intended as a package fumigant in or on dried prunes and glace 1 fruit. It is also intended as a fumigant in or on bulk quantities of cocoa, gums, processed spices, starch, and processed nutmeats (except peanuts) when such bulk foods are to be further processed into a final food form.

(b) Except in the fumigation of packaged dried prunes and glace 1 fruits, it is applied in fumigation chambers not more than one time at a temperature not in excess of 125°F. The maximum period of fumigation shall not exceed 4 hours for cocoa, processed nutmeats (except peanuts), processed spices, and starch. For edible gums, the maximum duration shall be 24 hours.

(c) When used as described in paragraphs (a) and (b) of this section, residues shall not exceed the following limitations:

Food	Limitations [1]
Cocoa	300
Glace fruit	700 (as propylene glycol)
Gums	300
Processed nutmeats (except peanuts)	300
Prunes, dried	700 (as propylene glycol)
Spices, processed	300
Starch	300

[1] Expressed as parts per million of propylene oxide except where noted.

(d) When used as a mixture with carbon dioxide (92 parts of carbon dioxide to 8 parts of propylene oxide on a weight/weight basis), all commodities listed in paragraph (c) of this section, except glace 1 fruit and dried prunes, may be processed not more than one time for a period not to exceed 48 hours and at a temperature not to exceed 125 degrees F.

(e) To assure safe use of the additive, the label and labeling of the pesticide formulation containing the food additive shall conform to the label and labeling registered by the U.S. Environmental Protection Agency.

[40 FR 14156, Mar. 28, 1975, as amended at 41 FR 1589, Jan. 9, 1976. Redesignated at 41 FR 26568, June 28, 1976 and amended at 42 FR 59852, Nov. 22, 1977]

§ 193.390 Pyrethrins.

The food additive pyrethrins may be safely used in accordance with the following prescribed conditions:

(a) It is used or intended for use in combination with piperonyl butoxide for control of insects:

(1) In cereal grain mills and in storage areas for milled cereal grain products, whereby the amount of pyrethrins is from 10 percent to 100 percent of the amount of piperonyl butoxide in the formulation.

(2) On the outer ply of multiwall paper bags of 50 pounds or more capacity in amounts not exceeding 6 milligrams per square foot, whereby the amount of pyrethrins is equal to 10 percent of the amount of piperonyl butoxide in the formulation. Such

treated bags are to be used only for dried foods.

(3) On cotton bags of 50 pounds or more capacity in amounts not exceeding 5.5 milligrams per square foot of cloth, whereby the amount of pyrethrins is equal to 10 percent of the amount of piperonyl butoxide in the formulation. Such treated bags are constructed with waxed paper liners and are to be used only for dried foods that contain 4 percent fat or less.

(4) In two-ply bags consisting of cellophane/polyolefin sheets bound together by an adhesive layer when it is incorporated in the adhesive. The treated sheets shall contain not more than 10 milligrams of pyrethrins per square foot (107.6 milligrams per square meter). Such treated bags are to be used only for packaging prunes, raisins, and other dried fruits and are to have a maximum ratio of 0.31 milligram of pyrethrins per ounce of fruit (0.01 milligram of pyrethrins per gram of product).

(5) In food processing areas and food storage areas: *Provided*, That the food is removed or covered prior to such use.

(b) It is used or intended for use in combination with piperonyl butoxide and *N*-octylbicycloheptene dicarboximide for insect control in accordance with § 193.320.

(c) A tolerance of one part per million is established for residues of pyrethrins in or on:

(1) Milled fractions derived from cereal grains when present as a result of its use in cereal grain mills and in storage areas for milled cereal grain products.

(2) Dried foods when present as the result of migration from its use on the outer ply of multiwall paper bags of 50 pounds or more capacity.

(3) Foods treated in accordance with § 193.320.

(4) Dried foods that contain 4 percent fat, or less, when present as a result of migration from its use on the cloth of cotton bags of 50 pounds or more capacity constructed with waxed paper liners.

(5) Foods treated in accordance with paragraphs (a)(4) and (a)(5) of this section.

(d) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(e) Where tolerances are established under sections 408 and 409 of the Act on both raw agricultural commodities and processed foods made therefrom, the total residues of pyrethrins in or on the processed food shall not be greater than that permitted by the larger of the two tolerances.

§ 193.400 Simazine.

Tolerances are established for residues of the herbicide simazine (2-chloro-4,6-bis(ethylamino)-*s*-triazine) or simazine and its metabolites 2-amino-4-chloro-6-ethylamino-*s*-triazine and 2,4-diamino-6-chloro-*s*-triazine as follows:

1 part per million for residues of simazine in sugarcane byproducts (molasses and sirup), resulting from application of the herbicide to the growing crop sugarcane.

0.5 part per million for combined residues of simazine and its metabolities 2-amino-4-chloro-6-ethylamino-*s*-triazine and 2,4-diamino-6-chloro-*s*-triazine in potable water. Such residues may be present therein only as a result of the application of the herbicide on aquatic plants under an experimental permit which expires October 22, 1975, in connection with a temporary pesticide tolerance for residues of the herbicide and the metabolites in fish, such temporary pesticide tolerance expiring the same date as the experimental permit.

0.01 part per million for combined residues of simazine and its metabolites (2-amino-4-chloro-6-ethylamino-s-triazine and 2,4-diamino-6-chloro-s-triazine) in potable water when present therein as a result of application of the herbicide to growing aquatic weeds.

[40 FR 14156, Mar. 28, 1975, as amended at 40 FR 14592, Apr. 1, 1975. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.410 Daminozide.

Tolerances are established for residues of the plant regulator daminozide (butanedioic acid mono (2,2-dimethylhydrazide)) in the following processed foods when present therein as a result of the application of this pesticide to growing crops:

320 parts per million in concentrated tomato products.
135 parts per million in dried prunes.

(Sec. 409(c)(1), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(1)) transferred to the Administrator EPA in Reorganization Plan No. 3 (35 FR 15623))

[40 FR 42343, Sept. 12, 1975. Redesignated at 41 FR 26568, June 28, 1976]

§ 193.415 Tebuthiuron.

A tolerance of 0.3 part per million is established for residues of the herbicide tebuthiuron (N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N′-dimethylurea) in sugarcane sirup and molasses resulting from application of the herbicide to growing sugarcane. Such residues may be present therein only as a result of application of the herbicide in an experimental use program which expires March 26, 1981. Residues not in excess of this tolerance remaining after expiration of this program will not be considered actionable if the herbicide is legally applied during the term and in accordance with the provisions of the experimental use permit/food additive tolerance.

[42 FR 23149, May 6, 1977, as amended at 44 FR 19187, Apr. 2, 1979]

§ 193.418 [(1R,3S)3[(1′RS)(1′,2′,2′,2′-Tetrabromoethyl)]-2,2-dimethylcyclopropanecarboxylic acid (*S*)-alpha-cyano-3-phenoxybenzyl ester].

A regulation is established to permit the combined residues of the insecticide [(1*R*,3*S*)3[(1′*RS*)(1′,2′,2′,2′-tetrabromoethyl)]-2,2-dimethylcyclopropanecarboxylic acid (*S*)-alpha-cyano-3-phenoxybenzyl ester] and its metabolites (*S*)-alpha-cyano-3-phenoxybenzyl(1*R*,3*R*)-cis,trans-2,2-dimethyl-3-(2,2-dibromovinyl-cyclopropanecarboxylate calculated as parent in or on the following food commodities:

Commodities	Parts per million
Cottonseed oil	0.20

[50 FR 37846, Sept. 18, 1985]

§ 193.420 Tetradifon.

Tolerances are established for residues of tetradifon (2,4,5,4′-tetrachlorodiphenyl sulfone) when present as a result of its application as a pesticide chemical to growing agricultural crops, as follows:

120 parts per million in or on dried hops.
10 parts per million in or on dried figs.
8 parts per million in or on dried tea.

§ 193.430 Tricyclohexyltin hydroxide.

Tolerances are established for combined residues of the insecticide tricyclohexyltin hydroxide and its organotin metabolites (calculated as tricyclohexyltin hydroxide) in or on the following processed foods when present therein as result of application of the insecticide to the growing crops:

90 parts per million in dried hops.
4 parts per million in dried prunes.

§ 193.440 Trifluralin.

Tolerances are established for residues of the herbicide trifluralin in or on peppermint oil and spearmint oil at 2 parts per million when present therein as a result of application of the herbicide to the growing crops.

§ 193.450 Toxaphene.

A tolerance of 6 parts per million is established for residues of the insecticide toxaphene (chlorinated camphene containing 67 to 69 percent chlorine) in crude soybean oil when present therein as a result of the application of this insecticide to the growing soybean crop.

[51 FR 46617, Dec. 24, 1986]

§ 193.460 Zinc ion and maneb coordination product.

Tolerances are established for residues of a fungicide which is a coordination product of zinc ion and maneb (manganous ethylenebisdithiocarbamate) containing 20 percent manganese, 2.5 percent zinc, and 77.5 percent ethylenebisdithiocarbamate (the whole product calculated as zinc ethylenebisdithiocarbamate) in or on the following processed foods, when present therein as a result of the application of this fungicide to growing crops:

28 parts per million in raisins.
20 parts per million in the bran of barley, oats, rye, and wheat.
1 part per million in the flours of barley, oats, rye, and wheat.

§ 193.462 Oryzalin.

A regulation is established permitting residues of the herbicide oryzalin (3,5-dinitro-N^4, N^4 dipropylsulfanilamide) resulting from application of the pesticide to the growing crops in the following food commodities:

Foods	Parts per million
Peppermint (oil)	0.1
Spearmint (oil)	0.1

[48 FR 5900, Feb. 9, 1983]

§ 193.463 Ethyl 3-methyl-4-(methylthio)phenyl (1-methylethyl)-phosphoramidate.

Tolerances are established for the combined residues of the nematocide ethyl 3-methyl-4-(methylthio)phenyl (1-methylethyl)-phosphoramidate and its cholinesterase-inhibiting metabolites ethyl 3-methyl-4-(methylsulfinyl)phenyl (1-methylethyl)-phosphoramidate and ethyl 3-methyl-4-(methylsulfonyl)-phenyl (1-methylethyl) phosphoramidate in or on the following food commodities:

Foods	Parts per million
Citrus oil	25.0
Raisins	0.3

[48 FR 29839, June 29, 1983]

§ 193.464 Resmethrin.

Tolerances are established for residues of the insecticide resmethrin [5-(phenylmethyl)-3-furanyl] methyl 2,2-dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate in or on food items at 3.0 ppm resulting from use of the insecticide in food handling and storage areas as a space concentration for spot/or crack and crevice treatment and shall be limited to a maximum of 3.00 percent of the active ingredient by weight, and as a space treatment shall be limited to a maximum of 0.5 fluid ounce of 3.0 percent active ingredient by weight per 1000 cubic feet of space provided that the food is removed or covered prior to such use. To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and shall be used in accordance with such label and labeling.

[48 FR 36247, Aug. 10, 1983]

§ 193.465 Dicamba.

Tolerances are established for the combined residues of the herbicide dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-*o*-anisic acid in or on the following processed foods when present therein as a result of application of this herbicide to growing crops.

Foods	Parts per million
Sugarcane molasses	2.0

[48 FR 11114, Mar. 16, 1983]

§ 193.466 Fluazifop-butyl.

Tolerances are established for residues of (±)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid (fluazifop), both free and conjugated, and of (±)-butyl 2[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate (fluazifop-butyl), all expressed as fluazifop, in or on the following foods:

Foods	Parts per million
Cottonseed, oil	0.2
Soybean, oil	2.0

[48 FR 19023, Apr. 27, 1983]

§ 193.467 Imazalil.

Tolerances are established for the combined residues of the fungicide imazalil 1-[2-(2,4-dichlorophenyl)-2-(2-

propenyloxy)ethyl]-1*H*-imidazole and its metabolite 1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol in or on the following food commodity:

Foods	Parts per million
Citrus oil	25.0

[48 FR 28433, June 22, 1983]

§ 193.468 Pirimiphos-methyl.

(a) [Reserved]

(b) Interim tolerances are established for the combined residues of the insecticide pirimiphos-methyl (*O*-[2-(diethylamino)-6-methyl-4-pyrimidinyl] *O,O*-dimethylphosphorothioate, the metabolite *O*-(2-ethylamino-6-methylpyrimidin-4-yl) *O,O*-dimethylphosphorothioate and in free and conjugated form the metabolites 2-diethylamino-6-methylpyrimidin-4-ol, 2-ethylamino-6-methylpyrimidin-4-ol and 2-amino-6-methylpyrimidin-4-ol resulting from application of the insecticide to the stored commodities with tolerance limitations in or on the following food commodities:

Foods	Parts per million	Expiration date
Peanut oil	50.0	Sept. 27, 1985.
Rice, milling fractions	50.0	Do.
Wheat, milling fractions	50.0	Do.

(c) Tolerances are established for the combined residues of the insecticide pirimiphos-methyl (*O*,-[2-diethylamino-6-methyl-4-pyrimidinyl] *O,O*-dimethylphosphorothioate and its metabolite *O*-(2-ethylamino-6-methylpyrimidin-4-yl) *O,O*-dimethyl phosphorothioate and, in free and conjugated forms, the metabolites 2-diethylamino-6-methyl-pyrimidin-4-ol, 2-ethylamino-6-methyl-pyrimidin-4-ol, and 2-amino-6-methyl-pyrimidin-4-ol in or on the following processed foods when present therein as a result of application to stored grains:

Foods	Parts per million
Corn milling fractions (except flour)	40
Corn oil	88
Sorghum milling fractions (except flour)	40

[48 FR 51454, Nov. 9, 1983; 48 FR 54970, Dec. 8, 1983, as amended at 49 FR 46737, Nov. 28, 1984; 51 FR 28224, Aug. 6, 1986]

§ 193.469 5-(4-Chlorophenyl)-2,3-diphenylthiophene.

(a) [Reserved]

(b) An interim tolerance of 100.0 parts per million is established for residues of the insecticide 5-(4-chlorophenyl)-2,3-diphenylthiophene in the food commodity citrus oil resulting from applications of this chemical to oranges and grapefruit in connection with an experimental program. The expiration date for this tolerance is December 9, 1984.

[48 FR 56371, Dec. 21, 1983]

§ 193.470 Thiabendazole.

A tolerance of 3 parts per million is established for residues of the fungicide thiabendazole [2-(4-thiazolyl) benzimidazole] in or on wheat milled fractions (except flour) resulting from applications of the fungicide to growing wheat.

[50 FR 14098, Apr. 10, 1985]

§ 193.471 Chlorpyrifos-methyl.

Tolerances are established for the combined residues of the insecticide chlorpyrifos-methyl (*O*,-*O*-dimethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate and its metabolite (3,5,6-trichloro-2-pyridinol) in or on the following processed feeds when present therein as a result of application to stored grains:

Foods	Parts per million
Barley milling fractions (except flour)	90
Oats milling fractions (except flour)	130
Sorghum milling fractions (except flour)	90
Rice milling fractions (except flour)	30
Wheat milling fractions (except flour)	30

[50 FR 26682, June 27, 1985]

Subpart B—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

§ 193.520 Malathion.

Malathion may be safely used for the control of insects during the drying of grapes (raisins) in compliance with § 193.260 by incorporation into paper trays in amounts not exceeding 100 milligrams per square foot.

(40 FR 14156, Mar. 28, 1975. Redesignated at 41 FR 26568, June 28, 1976, and amended at 50 FR 2958, Jan. 23, 1985)

PART 197—SEAFOOD INSPECTION PROGRAM

Subparts A—C [Reserved]

Subpart D—Inspection of Canned Oysters

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197.885 Inspection fees.

AUTHORITY: Sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371).

SOURCE: 42 FR 14661, Mar. 15, 1977, unless otherwise noted.

Subparts A—C [Reserved]

Subpart D—Inspection of Canned Oysters

§ 197.310 Application for inspection service.

(a) Applications for inspection service on canned oysters under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372a) shall be on forms supplied by the Food and Drug Administration. No application for a regular inspection period filed with the Food and Drug Administration after September 1 preceding such period in any year shall be considered unless the applicant shows substantial cause for failure to file such application on or before September 1 of such year. The opening date of the canning season in each State shall be the date set by the State agency responsible for controlling the opening date of the canning season in that State. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by a payment of $600.00 as prescribed by § 197.385(a)(1). Such deposit shall be paid in the manner prescribed by § 197.385(e).

(b) For the purpose of §§ 197.310 through 197.385, an establishment is defined as a factory where oysters may be processed and warehouses under the control and direction of the packer where such canned oysters are stored.

§ 197.312 Granting or refusing inspection service; cancellation of application.

(a) The Secretary of Health and Human Services may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 197.330.

(b) The Secretary may refuse to grant the inspection service at any establishment for cause. In case of refusal the applicant shall be notified of the reason therefor and shall have returned to him all advance payments and production deposits made, less any expenses incurred for preliminary inspection of the establishment, or for other purposes incident to such application.

(c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before an inspector is assigned to the establishment. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and production deposits made, less any salary and other expense incurred incident to such application.

§ 197.315 Suspension and withdrawal of inspection service.

(a) The Administration may suspend and the Secretary may withdraw inspection service in any establishment upon failure of the packer to comply with any applicable provision of §§ 197.310 through 197.385 or upon the dissemination by the packer or any person in privity with him of any representation that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Food and Drug Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

§ 197.320 Inspection periods.

(a) The regular inspection period in each establishment in which inspection service under §§ 197.310 through 197.385 is granted consists of 4 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after October 1 but not later than March 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefor, accompanied by a payment of $600.00, as prescribed by § 197.385(a)(3), is made at least 2 weeks in advance of the close of such preceding inspection period. Applications for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 197.385(a)(3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year.

(c) Upon request of the packer, and with the approval of the Food and Drug Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take the place of an extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors.

(d) The inspection service shall be continuous throughout the inspection period.

§ 197.325 Assignment of inspectors.

(a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 197.310 through 197.385 is granted. Thereafter, the Food and Drug Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection.

(b) Any inspector of the Food and Drug Administration shall have free access at all times to all parts of the establishment and to all fishing and freight boats and other conveyances dredging oysters for or transporting oysters to such establishments.

§ 197.329 Uninspected oysters excluded from inspected establishments.

(a) No establishment to which inspection service on canned oysters has been granted shall at any time thereafter can oysters that have not been so inspected, or handle or store in such establishment any canned oysters that have not been so inspected; but this paragraph shall not apply to an establishment after termination of inspection service therein, or withdrawal therefrom as authorized by § 197.315.

(b) All oysters delivered to or held in an inspected establishment may be subject to inspection, but certificates of inspection shall be issued under § 197.380 only on canned oysters.

§ 197.330 General requirements for plant and equipment.

(a) All exterior openings of the cannery, including those of the shucking sheds, shall be adequately screened, and roofs and exterior walls shall be tight. When necessary, fly traps, fans, blowers, or other approved insect-control devices shall be installed.

(b) Shucking sheds and packing rooms shall be separate, and fixtures and equipment shall be so constructed and arranged as to permit thorough cleaning. Such sheds and rooms shall be adequately lighted and ventilated, and the floors shall be tight and arranged for thorough cleaning and proper drainage. Open drains from shucking shed shall not enter packing room. If shucking shed and packing room are in separate buildings, such buildings shall be not more than 100 yards apart, unless adequate provisions are made to enable efficient inspection.

(c) All surfaces of washers, tanks, belts, tables, flumes, utensils, and other equipment with which unshucked or shucked oysters come in contact after delivery to the establishment shall be of metal or of other smooth nonporous and easily cleanable material, provided such materials are not lead or other toxic substances. Metal seams shall be smoothly soldered or smoothly welded. Shucking tables shall be so constructed as to preclude contamination of working surfaces or products thereon from foot traffic or wheelbarrows or other containers used in delivering steamed oysters to such tables.

(d) Adequate supplies of suitable detergents and sanitizing agents approved by the Food and Drug Administration; clean, unpolluted running water; and steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

(e) Adequate toilet facilities of sanitary type which comply fully with applicable State laws and local ordinances shall be provided.

(f) An adequate number of sanitary washbasins, with liquid or powdered soap, shall be provided in both the shucking shed and the packing room. Paper towels shall be provided in the packing room.

(g) Signs requiring employees handling oysters to wash their hands after each absence from post of duty shall be conspicuously posted in the shucking shed and packing room and elsewhere about the premises as conditions require.

(h) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the oysters before delivery for steaming or other means of opening.

(i) If steam boxes are used for opening the oysters, they shall be provided with adequate steam inlets, exhausts, drains, a safety valve, and a pressure gauge.

(j) Suitable means shall be provided for removing shells and debris from shucking shed.

(k) One or more suitable devices shall be provided for removing shell and grit from shucked oysters, for washing such oysters, and for their subsequent drainage.

(l) One or more suitable inspection belts shall be installed for the inspection of shucked oysters.

(m) Equipment shall be provided for code-marking cans.

(n) An automatic container-counting device shall be installed in each cannery line.

(o) Each sterilizing retort shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperatures.

(2) An indicating mercury thermometer of a range from 170° F to 270° F, with scale divisions not greater than 2° F, installed either within a fitting attached to the shell of the retort or within the door or shell of the retort. If the thermometer is installed within a fitting, such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least one-eighth inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.

(3) A recording thermometer of a range from 170° F to 270° F, with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 5 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.

(5) A blow-off vent of at least ¾-inch inside diameter in the top of the retort.

(6) A ⅛-inch bleeder in top of the retort.

(p) Suitable space and facilities shall be provided for the inspector to prepare records and examine samples and for the safekeeping of records and equipment.

§ 197.340 General operating conditions.

(a) The decks and holds of all boats tonging or dredging oysters for or transporting oysters to an inspected establishment, and the bodies of other conveyances so transporting oysters shall be kept in a sanitary condition. Such boats shall be equipped with adequate means for protecting the oysters against contamination with bilge water.

(b) Inspected establishments, freight boats, and other conveyances serving such establishments shall accept only live, clean, sound oysters taken from unpolluted areas. When necessary, ice or other suitable refrigeration shall be provided to prevent spoilage.

(c) After delivery of each load of oysters to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

(d) Before being steamed or opened by other means, the oysters shall be washed with clean, unpolluted water and then passed over the inspection belt and culled to remove dirty, muddy, dead, or decomposed oysters and extraneous material. Muddy oysters may be returned to the washer for rewashing.

(e) As often as is necessary to maintain sanitary conditions, unloading platforms and equipment shall be washed with clean, unpolluted water, and all debris shall be cleaned therefrom.

(f) Shells shall be removed from the shucking shed continuously.

(g) Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in the cannery or, except for shells, about the premises. Shells shall not be allowed to accumulate about the premises in such a manner as to create a nuisance.

(h) The delivery of steamed oysters to shuckers by means of manually rolling, trundling, or wheelbarrowing such oysters on or above shucking tables will not be permitted.

(i) Shucking knives and shucking cups shall be thoroughly washed with soap and water and chlorinated before use each day. Chlorine solution shall be maintained at a strength of 200 parts per million.

(j) No shucked oysters shall be returned to shucker after delivery to the weigher. Shucking cups shall be cleaned and sanitized after each delivery to the weigher.

(k) Shucked oysters being transported from one building to another shall be properly covered and protected against contamination.

(l) The shucked oysters shall be washed, separated from the shell and grit by suitable devices, and then immediately drained. The time of washing shall not exceed the minimum time necessary for cleansing.

(m) From the time of delivery to the cannery up to the time of final processing, oysters shall be handled expeditiously and under such conditions as to prevent contamination or spoilage.

(n) The packer shall destroy for food purposes under the immediate supervision of the inspector all oysters in his possession condemned by the inspector as filthy, decomposed, putrid, or unfit for food. Oysters condemned on the boat or on the unloading platform shall not be taken into the cannery, but shall be either destroyed or returned to a bedding ground.

(o) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.

(p) All floors and other parts of the establishment, including unloading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition.

(q) The packer shall require all employees handling oysters to wash their hands after each absence from post of duty and to observe other proper habits of cleanliness.

(r) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease or with any open sores on exposed portions of the body.

§ 197.350 Code marking.

(a) Code marks shall be affixed to all cans and other immediate containers before they are placed in the processing retorts. Such marks shall show at least:

(1) The date of packing;

(2) The establishment where packed;

(3) The conveyance; and

(4) The size of the oysters when such oysters are graded for size.

(b) Keys to all code marks shall be given to the inspector.

(c) Each lot shall be stored separately pending final inspection, with a space of not less than 6 inches between stacks of each lot. For the purposes of the regulations in this part all cans or other containers bearing the same code marks shall be regarded as comprising a lot.

§ 197.355 Processing.

(a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned oysters shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimum employed for the containers indicated:

CANNED OYSTERS

Size	Initial temperature (degrees Fahrenheit)	Time at 240° F (minutes)	Time at 250° F (minutes)
211 by 212			
211 by 300	70	24	14
211 by 306	130	23	13
211 by 400			
307 by 400	70	28	14
307 by 409	130	27	13

For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is admitted to the sterilizing retort.

(c) The blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The inspector shall identify each record on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Food and Drug Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(e) The packer shall keep for at least 2 years all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Food and Drug Administration.

§ 197.360 Examination after canning.

(a) Adequate samples shall be drawn by the inspector from each lot of canned oysters and shall be examined to determine whether or not such canned oysters conform to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all canned oysters condemned by the inspector as not complying with § 197.355, or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 197.370 Labeling.

(a) Labels on canned oysters packed and certified under §§ 197.310 through 197.385 may bear the mark "Production Supervised by the U.S. Food and Drug Administration." Such mark, if used, shall be plainly and conspicuously displayed, in type of uniform size and style, on a strongly contrasting, uniform background.

(b) Two proofs, or one proof and one photostat thereof, or eight specimens of all labeling intended for use on inspected canned oysters or on or within the cases therefor shall be submitted to the Food and Drug Administration for approval. If the proofs or photostat and proof are submitted, eight specimens of the labeling shall be sent to the Food and Drug Administration after printing. The Food and Drug Administration is hereby authorized to approve labeling for use on canned oysters inspected under §§ 197.310 through 197.385. Approval shall be subject to the condition that such labeling shall be so used as to comply with the provisions of the Federal Food, Drug and Cosmetic Act, amendments, thereto, and regulations thereunder. The Food and Drug Administration is also authorized to revoke any such approval for cause. The Food and Drug Administration shall not approve labeling for canned oysters intended for export under the provisions of § 197.380(e).

(c) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (b) of this section and bearing the mark described in paragraph (a) of this section, and no labeling simulating any such approved labeling, shall be used after such approval on canned oysters other than those that have been handled, prepared, and packed in compliance with all provisions of §§ 197.310 through 197.385; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 197.315 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Food and Drug Administration that the use of such labeling on inspected canned oysters has been discontinued and will not be resumed.

(d) Canned-oyster labeling authorized by paragraph (a) of this section or approved under paragraph (b) of this section shall be used only as authorized by §§ 197.310 through 197.385. Unauthorized use of such labeling renders the user liable to the penalties prescribed by the Food, Drug, and Cosmetic Act, as amended.

§ 197.380 Certificates of inspection; warehousing and export permits.

(a) After finding that the canned oysters comprising any parcel have been handled, prepared, and packed in compliance with all provisions of §§ 197.310 through 197.385; bear labeling approved as authorized under § 197.370(b); and comply with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such canned oysters so comply. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place where such parcel is stored, the size and kind of containers, the commercial brand name on the labels, the condition of the oysters if they are broken or if they are substandard in fill, and the destination of the lot if known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced; but such canned oysters may be relabeled under supervision of an inspector and recertified if the inspector finds that, after being relabeled, they comply with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, canned oysters shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.360(b).

(c) Applications to move unlabeled canned oysters for storage in a warehouse elsewhere than in the establishment where such oysters were packed shall be on forms supplied by the Administration. The application shall give the name and location of the warehouse in which such canned oysters are to be stored, and shall be accompanied by an agreement signed by the operator of such warehouse that inspectors shall have free access at all times to all canned oysters so stored, and that conditions which will preserve the identity of each parcel of such canned oysters shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the canned oysters comprising any parcel have been packed in compliance with §§ 197.310 through 197.385 and conform, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such canned oysters. Such permit shall specify the code marks to which it applies, the quantity of the parcel so marked, the place from and to which such parcel is to be moved, the size of the oysters, the size and kind of containers, and the condition of the oysters if they are broken or if they are substandard in fill and, if such be the case, that they are intended for export under paragraph (e) of this section. When any provision of the agreement is violated, the Food and Drug Administration may revoke any permit issued pursuant to such agreement, and may also revoke its approval of the application for warehousing which accompanied such agreement.

(d) Unless covered by certificate, canned oysters stored under the authority of paragraph (c) of this section shall be moved from the warehouse where stored only for re-storage under such authority, or for return upon written permission of the inspector to the establishment where packed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.360(b).

(e) An application to export canned oysters under the provisions of section 801(d) of the act shall be accompanied by the original or a verified copy of the specifications of the foreign purchaser; if required by the Food and Drug Administration, evidence showing that such canned oysters are not in conflict with the laws of the country to which they are intended for export; and, if shipment of labeled canned oysters is specified or directed, eight specimens of the labeling therefor. If canned oysters prepared or packed according to such specifications are not in conflict with the laws of such country, the Administration shall direct the inspector to issue to the applicant an export permit covering such canned oysters comprising any parcel ordered by such purchaser under such specifications, when the inspector finds that such canned oysters were packed in compliance with the requirements of §§ 197.310 through 197.385 regarding sanitary conditions and processing; are not filthy, decomposed, putrid, or otherwise unfit for food; accord to such specifications, and are labeled on the outside of the shipping package to show that they are intended for export. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such canned oysters were packed under sanitary conditions, are wholesome, and accord to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such canned oysters.

§ 197.385 Inspection fees.

(a)(1) Except as otherwise provided by the regulations in this part, an initial payment of $600.00 shall accompany each application; thereafter, three additional advance payments of $600.00 each shall be made, as follows: One payment on or before the date of the beginning of the regular inspection period specified in the application for inspection; the remaining two payments on or before the first day of each succeeding month, except that the Food and Drug Administration may require the full amount of all advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season: *Provided*, That a packer who is concurrently receiving inspection service and making payments under the regulations for the inspection of processed shrimp shall not make any additional payments under this subparagraph.

(2) Whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: *Provided*, That in the event of a determination described in this subparagraph the total payments and production deposits made by the packer involved shall be charged with the cost of the service made available for the establishment, without regard to the method provided hereinafter for computing charges against payments and production deposits, and the balance of the total payments and deposits remaining after such charges shall be refunded by the Food and Drug Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b)(1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of oysters canned by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Food and Drug Administration on an estimate of production authorizes other amounts, and shall be computed at the rate of 15 cents for each case of 48 cans, size 211 x 300. Any advance production deposits in excess of those required for actual oysters canned for the fiscal year (July 1 through June 30) will be refunded to the packers by the Food and Drug Administration after the completion of the fiscal year.

(2) Production deposits as computed under paragraph (b)(1) of this section, together with deposits for shrimp received as prescribed under § 197.885(b)(1), in the case of processed shrimp, shall be charged with the balance of the total cost of the inspection service which has not been provided for by the combined total payments under paragraph (a) of this

section and paragraph (a) of § 197.885, in the case of processed shrimp. The balance of the production deposits remaining after such charges have been made shall be refunded by the Administration to the packers after the completion of the fiscal year in the ratio which each packer's production deposits for oysters canned and deposits for shrimp received bears to the combined total of such deposits for oysters canned and shrimp received by all packers for the fiscal year.

(3) When inspection service is withdrawn from an establishment as authorized under § 197.315(a), the Food and Drug Administration shall not return to the packer any advance payments and/or deposits required to the date of withdrawal of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the method described in this section, and the balance that would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses incurred in accordance with the regulations of the United States Government, for salary, travel, subsistence, and for other purposes incident to inspection for the purpose of issuing a certificate or warehousing or export permit on canned oysters stored or held at any place other than an establishment to which a seafood inspector is then assigned.

(d) When the cannery and the cannery warehouse of an establishment are located at different points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check, collectible at par drawn to the order of the Food and Drug Administration, and payable at Washington, DC. All such drafts and checks except those for the payment required by § 197.310(a), shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health and Human Services, Washington, DC, whereupon after appropriate records thereof have been made they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

Subparts E—H [Reserved]

Subpart I—Inspection of Processed Shrimp

§ 197.810 Application for inspection service.

(a) Applications for inspection service on the processing of shrimp under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act shall be on forms supplied by the Food and Drug Administration. The processing of shrimp comprises all the operations including labeling and storage, necessary to prepare for the market shrimp in any of the following forms: Iced or frozen raw headless, raw peeled or cooked peeled (any of which may be deveined); iced or frozen deveined shrimp, partially or completely peeled (which may be battered and breaded before freezing), and canned shrimp. No application for a regular inspection period filed with the Food and Drug Administration after May 1, preceding such period in any year, shall be considered unless the applicant shows substantial cause for failure to file such application on or before May 1 of such year. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by an advance payment of $500.00 as prescribed by § 197.885(a)(1). Such payment shall be made in the manner prescribed by § 197.885(e).

(b) For the purposes of §§ 197.810 through 197.885, an establishment is defined as a factory where shrimp may be processed and warehouses and cold storage plants under the control and direction of the packer where such shrimp is stored.

§ 197.812 Granting or refusing inspection service; cancellation of application.

(a) The Secretary of Health and Human Services may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 197.830.

(b) The Secretary may refuse to grant inspection service at any establishment for cause. In case of refusal, the applicant shall be notified of the reason therefor and shall have returned all advance payments and deposits made, less any expenses incurred for preliminary inspection of the establishment or for other purposes incident to such application.

(c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before July 1 preceding the inspection period covered by the application. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and deposits made, less any salary and other expense incurred incident to such application

§ 197.815 Suspension and withdrawal of inspection service.

(a) The Food and Drug Administration may suspend and the Secretary may withdraw inspection service in any establishment:

(1) Upon failure of the packer to comply with any applicable provision of §§ 197.810 through 197.885; or

(2) Upon the dissemination by the packer or any person in privity with him of any representation that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Food and Drug Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

§ 197.820 Inspection periods.

(a) The regular inspection period in each establishment in which inspection service under §§ 197.810 through 197.885 is granted consists of 9 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after July 1, but not later than October 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date, then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefor, accompanied by a payment of $600.00 as prescribed by § 197.885(a)(3), is made at least 2 weeks in advance of the close of such preceding inspection period. Applications for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 197.885(a)(3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year.

(c) Upon request of the packer, and with the approval of the Food and Drug Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take the place of an extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors.

(d) The inspection service shall be continuous throughout the inspection period.

§ 197.825 Assignment of inspectors.

(a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 197.810 through 197.885 is granted. Thereafter, the Food and Drug Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection.

(b) Any inspector of the Food and Drug Administration shall have free access at all times to all parts of the establishment, to plants supplying materials to the inspected establishment, and to all fishing and freight boats and other conveyances catching shrimp for, or transporting shrimp to, such establishment.

§ 197.829 Uninspected shrimp excluded from inspected establishments.

(a) No establishment to which inspection service has been granted shall at any time thereafter process shrimp which has not been so inspected or handle or store in such establishment any processed shrimp which has not been so inspected; but this paragraph shall not apply to an establishment after termination of inspection service therein or withdrawal therefrom as authorized by § 197.815.

(b) All shrimp and other ingredients entering into the finished product may be subject to inspection prior to delivery to the establishment or at any time thereafter, and all shrimp processed in such establishment shall be subject to certification under § 197.880.

§ 197.830 General requirements for plant and equipment.

(a) All exterior openings of the establishment shall be adequately screened and roofs and exterior walls shall be tight. When necessary fly traps, fans, blowers, or other approved insect-control devices shall be installed.

(b) Except for raw headless shrimp which may or may not be deveined, picking and packing rooms shall be separate, provided that this requirement may be waived by the Food and Drug Administration where separation of picking and packing rooms is not necessary for adequate sanitation. Blanching tanks shall not be located in picking room. Fixtures and equipment shall be so constructed and arranged as to permit thorough cleaning. Such rooms shall be adequately lighted and ventilated, and the floors shall be tight and arranged for thorough cleaning and proper drainage. Open drains from picking room shall not enter packing or blanching room. If picking and packing rooms are in separate buildings, such buildings shall be not more than 100 yards apart unless adequate provisions are made to enable efficient inspection.

(c) All surfaces of tanks, belts, tables, flumes, utensils, and other equipment with which either picked or unpicked shrimp come in contact after delivery to the establishment shall be of metal or of other smooth nonporous and easily cleanable materials, provided such materials are not lead or other toxic substances. Metal seams shall be smoothly soldered or smoothly welded.

(d) Adequate supplies of suitable detergents and sanitizing agents approved by the Food and Drug Administration; clean, unpolluted running water; and, if necessary, steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

(e) Adequate toilet facilities of sanitary type which comply fully with applicable State laws and local ordinances shall be provided.

(f) An adequate number of sanitary washbasins, with liquid or powdered soap, shall be provided in both the picking and packing rooms. Paper towels shall be provided in the packing room. Provision shall be made for sanitizing the hands of employees by the use of suitable sanitizing agents.

(g) Signs requiring employees handling shrimp to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the picking and packing rooms and elsewhere about the premises as conditions require.

(h) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the shrimp before processing.

(i) Suitable containers, flumes, chutes, or conveyors shall be provided for removing offal from picking room.

(j) Picking or heading tables shall be equipped with flumes supplied with clean, unpolluted water or with mechanical conveyors for removing the picked or headed shrimp.

(k) Equipment shall be provided for code-marking cans and other immediate containers and master cartons used in packaging other than canned shrimp.

(l) An automatic container-counting device shall be installed in each cannery line.

(m) Each sterilizing retort shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperatures.

(2) An indicating mercury thermometer of a range from 170° F to 270° F with scale divisions not greater than 2° F. For steam cook such thermometer shall be installed either within a fitting attached to the shell of the retort or within the door or shell of the retort. For water cook such thermometers shall be installed in the door or shell of the retort below the water level. If the thermometer is installed within a fitting such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least one-eighth of an inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.

(3) A recording thermometer of a range from 170° F to 270° F with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 5 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.

(5) For steam cook, a blow-off vent of at least ¾-inch inside diameter in the top of the retort.

(6) For steam cook, a ⅛-inch bleeder in top of retort.

(n) Each cold storage compartment shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to indicate accurately the temperature within the storage compartment.

(3) A recording thermometer so installed as to indicate accurately the temperature within the compartment at all times. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(o) Provision shall be made for water-glazing where such glazing is necessary to maintain the quality of frozen shrimp. Glazing shall be done with clean, unpolluted water.

(p) Provision shall be made for immediate icing or cold storage of all packaged shrimp which is destined for sale as unfrozen shrimp.

(q) Suitable space and facilities shall be provided for the inspector to prepare records and examine samples, and for the safekeeping of records and equipment.

§ 197.840 General operating conditions.

(a) Plants supplying raw headless or frozen raw headless shrimp to an inspected establishment, decks and holds of all boats catching shrimp for or transporting shrimp to an inspected establishment, and the bodies of other conveyances so transporting shrimp shall be kept in a sanitary condition.

(b) Inspected establishments, plants supplying inspected establishments, freight boats, and other conveyances serving such establishments shall accept only fresh, clean, sound shrimp. The shrimp shall be iced or refrigerated immediately after they are caught, and shall be kept adequately iced or refrigerated until delivery to the establishment.

(c) After delivery of each load of shrimp to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

(d) Before being headed, picked, or deveined, the shrimp shall be adequately washed with clean, unpolluted water and then passed over the inspection belt and culled to remove all shrimp that are filthy, decomposed, putrid, or otherwise unfit for food, and all extraneous material.

(e) Offal from picking tables shall not be piled on the floor, but shall be placed in suitable containers for frequent removal, or shall be removed by flumes, conveyors, or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the establishment.

(f) Shrimp shall be picked into flumes that immediately remove the picked meats from the picking tables; except that shrimp may be picked into seamless containers of not more than 3 pints capacity if the picked meats are not held in such containers for more than 20 minutes before being flumed or conveyed from the picking tables. If shrimp are picked into such containers, the containers shall be cleaned and sanitized as often as may be necessary to maintain them in a sanitary condition, but in no case less frequently than every 2 hours. Whenever a picker is absent from his or her post of duty, the container used by such picker shall be cleaned and sanitized before picking is resumed. For the purposes of this paragraph, the term "picked" shall include the operation whereby a portion of the shell is removed, leaving the tail in place, and the back of the shrimp is sliced open to remove the alimentary canal or vein.

(g) Picked shrimp being transported from one building to another shall be properly covered and protected against contamination.

(h) From the time of delivery to the establishment up to the time of final processing, shrimp shall be handled expeditiously and under such conditions as to prevent contamination or spoilage. Shrimp other than that to be canned shall be precooled immediately after the final cleaning or blanching operation to a temperature not exceeding 50° F if it is to be packaged immediately, or to a temperature not exceeding 40° F if it is not to be packaged immediately. If such shrimp are to be frozen, they shall be placed in the freezing compartment within 1 hour after final preparation.

(i) If batter is employed, it shall be used within 1 hour after it is prepared. The temperature of the batter shall not exceed 50° F.

(j) The packer shall destroy for food purposes under the immediate supervision of the inspector all shrimp in his possession condemned by the inspector as filthy, decomposed, putrid, or otherwise unfit for food. Shrimp condemned on boat or unloading platform shall not be taken into the icebox or picking room.

(k) Raw materials other than shrimp that enter into the finished product shall not be used if condemned by the inspector as unfit for food. Such condemned raw materials shall be segregated from usable materials and be held for disposal as directed by the inspector, or they may be destroyed forthwith by the packer if he so desires.

(l) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.

(m) All floors and other parts of the establishment, including unloading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition. Containers for mixing or holding batter shall be adequately cleaned and sanitized before they are used for a new batch of batter. Equipment for applying batter shall be adequately cleaned and sanitized at least once each hour while in operation.

(n) The packer shall require all employees handling shrimp to wash and sanitize their hands after each absence from post of duty, and to observe other proper habits of cleanliness.

(o) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease, or with any open sores on exposed portions of the body.

§ 197.850 Code marking.

(a) Permanently legible code marks shall be placed on all immediate containers at the time of packaging. Such marks shall show at least:

(1) The date of packing;

(2) The establishment where packed; and

(3) The size of the shrimp when such shrimp are graded for size and are not in containers through which they are clearly visible.

Corresponding code marks shall also be placed on the master cartons containing individual packages of shrimp other than canned.

(b) Keys to all code marks shall be given to the inspector.

(c) Each lot shall be stored separately pending final inspection, with a space of not less than 6 inches between stacks of each lot. For the purposes of the regulations in this part, all cans or other containers bearing the same code marks shall be regarded as comprising a lot.

§ 197.855 Processing.

(a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned shrimp shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimums employed for the containers indicated:

DRY PACK

Kind of container and liner	Size	Initial temperature	Time at 240° F (minutes)	Time at 250° F (minutes)
Tin: 1-piece liner	211 by 400 and smaller	70° F	80	60
	do	70° F	70	50
No liner	307 by 208	70° F	70	50
	307 by 400	70° F	75	55

WET PACK

Kind of container and size	Initial temperature	Time at 240° F (minutes)	Time at 250° F (minutes)
Tin:			
211 by 400 (and smaller)	90° F	25	13
307 by 208	90° F	25	13
307 by 400	90° F	25	13
502 by 510	90° F	27	16
Glass: 2 to 9 fluid ounces, inclusive		22	14

For wet-pack shrimp in cans 307 x 400 and smaller, a cook of 12 minutes at 250° F, and for wet-pack shrimp in cans 502 x 510, a cook of 15 minutes at 250° F, may be approved if adequate provisions are made to insure an initial temperature of not less than 120° F in each individual can. For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is admitted to the sterilizing retort.

(c) For steam cook, blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The method of freezing is not specified by the regulations in this part. Whatever method is used must be such as will produce a hard-frozen product in a sufficiently short time to prevent decomposition. Bulk packages containing 5 pounds or more of shrimp per package shall be hard frozen within 24 hours; smaller packages should be hard frozen within 12 hours. After freezing, the shrimp shall be stored in such a manner that its temperature does not exceed 0° F, and shall be handled in such manner as will maintain the hard-frozen condition.

(e) The storage temperatures for shrimp that are not frozen or canned are as follows:

(1) Cooked and peeled shrimp shall be stored at a room temperature not exceeding 35° F.

(2) Raw headless shrimp shall be stored at a room temperature not exceeding 35° F, except that it may be stored at a higher room temperature if sufficiently iced at all times to prevent spoilage.

(f) The inspector shall identify each record on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Food and Drug Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(g) The packer shall keep for at least 2 years all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Food and Drug Administration.

§ 197.860 Examination after processing.

(a) Adequate samples shall be drawn by the inspector from each lot of processed shrimp and shall be examined to determine whether or not such processed shrimp conforms to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all processed shrimp condemned by the inspector as not complying with § 197.855(a), or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 197.870 Labeling.

(a) Labels on shrimp packed and certified under §§ 197.810 through 197.885 may bear a mark attesting to such packing and certification. Depending upon the type of processing, such marks, if used, shall read as follows:

(1) For canned shrimp: "Production supervised by U.S. Food and Drug Administration."

(2) For frozen shrimp: "Packing and freezing supervised by U.S. Food and Drug Administration. Perishable product—Not warranted against mishandling after freezing."

(3) For fresh, iced, or refrigerated shrimp: "Packing supervised by U.S. Food and Drug Administration. Perishable product—Not warranted against mishandling after packing." Such marks if used shall be plainly and conspicuously displayed in type of uniform size and style on a strongly contrasting uniform background. The marks referred to in paragraph (a) (2) and (3) of this section shall not be used on the master carton unless such marks will be defaced by the opening of the cartons.

(b) Labels on inspected processed shrimp, other than canned shrimp, not bearing the marks referred to in paragraph (a) (2) and (3) of this section, and all master cartons for inspected shrimp other than canned shrimp, shall bear the statement "Perishable—Keep frozen" or "Perishable—Keep refrigerated," whichever is applicable to the product.

(c) Two proofs, or one proof and one photostat thereof, or eight specimens of all labeling intended for use on inspected shrimp, or on or within the cases therefor, shall be submitted to the Food and Drug Administration for approval. If proofs or photostat and proof are submitted, eight specimens of the labeling shall be sent to the Food and Drug Administration after printing. The Food and Drug Administration is authorized to approve labeling for use on or with processed shrimp inspected under §§ 197.810 through 197.885; approval shall be subject to the condition that such labeling shall be so used as to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto and regulations thereunder. The Food and Drug Administration is also authorized to revoke any such approval for cause. The Food and Drug Administration shall not approve labeling for processed shrimp intended for export under the provisions of § 197.880(e).

(d) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (c) of this section and bearing the marks described in paragraph (a) of this section, and no labeling simulating any such approved labeling, shall be used, after such approval, on processed shrimp other than that which has been handled, prepared, packed, and stored in compliance with all provisions of §§ 197.810 through 197.885; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 197.815 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Food and Drug Administration that the use of such labeling on inspected processed shrimp has been discontinued and will not be resumed.

(e) Shrimp labeling authorized by paragraph (a) of this section or approved under paragraph (c) of this section shall be used only as authorized by §§ 197.810 through 197.885. Unauthorized use of such labeling renders the user liable to the penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended.

§ 197.880 Certificates of inspection; warehousing and export permits.

(a) After finding that the processed shrimp comprising any parcel has been handled, prepared, and packed in compliance with all provisions of §§ 197.810 through 197.885, bears labeling approved as authorized under § 197.870(c), and complies with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such processed shrimp so complies. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place where such parcel is stored, the size of the shrimp, the size and kind of containers, the type of pack, the commercial brand name on the labels, the quality grade of the shrimp if it is fancy, the condition of the shrimp if it is broken or if it is substandard in fill and the destination of the lot if known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced, or if mishandling, improper storage, or other circumstances so change the product that it no longer complies with the requirements for the issuance of a certificate; but such processed shrimp may be relabeled under the supervision of an inspector and recertified if the inspector finds that, after being relabeled, it complies with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, processed shrimp shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.860(b).

(c) Applications to move unlabeled processed shrimp for storage in a warehouse or cold storage plant elsewhere than in the establishment where such shrimp was processed shall be on forms supplied by the Food and Drug Administration. The application shall give the name and location of the warehouse or cold storage plant in which such processed shrimp is to be stored, and shall be accompanied by an agreement signed by the operator of such warehouse or cold storage plant that inspectors shall have free access at all times to all processed shrimp so stored and that conditions which will preserve the identity of each parcel of such processed shrimp shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the processed shrimp comprising any parcel has been packed in compliance with §§ 197.810 through 197.885 and conforms, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such processed shrimp. Such permit shall specify the code marks to which it applies, the quantity of the parcel so marked, the places from and to which such parcel is to be moved, the size of the shrimp, the size and kind of containers, the type of pack, whether or not it is fancy grade, the condition of the shrimp if it is broken or if it is substandard in fill, and, if such be the case, that it is intended for export under paragraph (e) of this section. When any provision of the agreement is violated, the Food and Drug Administration may revoke any permit issued pursuant to such agreement, and may also revoke its approval of the application for warehousing or cold storage which accompanied such agreement.

(d) Unless covered by certificate, processed shrimp stored under the authority of paragraph (c) of this section shall be moved from the warehouse or cold storage plant where stored only for re-storage under such authority, or for return upon written permission of the inspector to the establishment where processed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.860(b).

(e) An application to export processed shrimp under the provisions of section 801(d) of the act shall be accompanied by the original or a verified copy of the specifications of the foreign purchaser; if required by the Food and Drug Administration, evidence showing that such processed shrimp is not in conflict with the laws of the country to which it is intended for export; and, if shipment of labeled processed shrimp is specified or directed, eight specimens of the labeling therefor. If processed shrimp prepared or packed according to such specifications is not in conflict with the laws of such country, the Food and Drug Administration shall direct the inspector to issue to the applicant an export permit covering such processed shrimp comprising any parcel ordered by such purchaser under such specifications when the inspector finds that such processed shrimp was packed in compliance with the requirements of §§ 197.810 through 197.885 regarding sanitary conditions and processing; is not filthy, decomposed, putrid, or otherwise unfit for food, accords to such specifications; and is labeled on the outside of the shipping package to show that it is intended for export. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such processed shrimp was packed under sanitary conditions, is wholesome, and accords to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such processed shrimp.

§ 197.885 Inspection fees.

(a)(1) Except as otherwise provided by the regulations in this part, an initial payment of $500.00 shall accompany each application; thereafter, eight additional advance payments of $500.00 shall be made on or before the first day of each month beginning July 1 and continuing through February 1 for the regular inspection period; except that the Food and Drug Administration may require the full amount of advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season.

(2) Whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity, to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: *Provided*, That in the event of a determination described in paragraph (a)(2) of this section the total payments and deposits made by the packer involved shall be charged with the cost of the service made available for the establishment without regard to the method provided hereinafter for com-

puting charges against payments and deposits for shrimp received, and the balance of the total payments and deposits for shrimp received remaining after such charges shall be refunded by the Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b) (1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of shrimp received by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Food and Drug Administration on an estimate of receipt of shrimp authorizes other amounts, and shall be computed at the rate of 20 cents per 100 pounds of whole raw shrimp, or 35 cents per 100 pounds of raw headless shrimp, received by the plant. For the purposes of this section, the quantity of shrimp received by an establishment shall be determined by weighing on a suitable scale immediately after such shrimp leaves the initial inspection belt: *Provided, however,* That other arrangements for determining accurately the weight of shrimp received may be employed if approved in advance by the Food and Drug Administration. A record of such weights shall be maintained and made available to the inspector upon his request. Any advance deposits in excess of those required for actual shrimp received for the fiscal year (July 1 through June 30) shall be refunded to the packer by the Food and Drug Administration after the completion of the fiscal year.

(2) Deposits for shrimp received as computed under paragraph (b)(1) of this section, together with production deposits prescribed for oysters canned under § 197.385(b)(1), shall be charged with the balance of the total cost of the inspection service that has not been provided for by the combined total payments under paragraph (a) of this section and § 197.385(a), in the case of canned oysters. The balance of the deposits remaining for shrimp received after such charges have been made shall be refunded by the Food and Drug Administration to the packers after the completion of the fiscal year, in the ratio which each packer's deposits for shrimp received and production deposits for oysters canned bears to the combined total of such deposits for shrimp received and oysters canned by all packers for the fiscal year.

(3) When inspection service is withdrawn from an establishment as authorized under § 197.815(a), the Food and Drug Administration shall not return to the packer any advance payments and/or deposits required to the date of withdrawal of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the method described in this section, and the balance which would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses, incurred in accordance with the regulations of the United States Government for salary, travel, subsistence, and other purposes incident to inspection described under § 197.825(b) of suppliers of any materials to establishments under the inspection service or for the purpose of issuing a certificate or warehousing or export permit on processed shrimp stored or held at any place other than an establishment to which a seafood inspector is then assigned.

(d) When the processing plant and the warehouse or cold storage plant of an establishment are located at different points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check collectible at par drawn to the order of the Food and Drug Administration, and payable at Washington, DC. All such drafts and checks, except those for the payment required by § 197.810(a), shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health and Human Services, Washington, DC, whereupon after appropriate records thereof have been made, they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account, "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to the packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

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FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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21 CFR CHAPTER I (PARTS 170 TO 199)
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American Association of Oil Chemists 36 E. Wacker Dr., Chicago, IL 60601	
AOCS Method Trla-64T "Titer Test"	178.3780(b)(2)
AOCS Method Tlla-64T "Saponification Value"	178.3780(b)(3)
American Society for Testing and Materials 1916 Race St. Philadelphia, PA 19103	
ASTM D 5–73 (Reapproved 1978) Standard Method of Test for Penetration of Bituminous Materials.	176.170(a)(5)
ASTM D 36–76 Standard Test Method for Softening Point of Asphalts and Tar Pitches (Ring and Ball Apparatus).	176.170(a)(5)
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ASTM D 88–81 Standard Method of Test for Saybolt Viscosity	178.3870(f)(4); 178.3910
ASTM D 127–60 Standard Method of Test for Melting Point of Petrolatum and Microcrystalline Wax.	176.180(b)(2); 177.1200(c)
ASTM D 156–82 Standard Method of Test for Saybolt Color of Petroluem Products (Saybolt Chromometer Method).	178.3620(b)(1)(i); 178.3910(a)(4)(i)(*c*)
ASTM D 381–80 Standard Method of Test for Existent Gum in Fuels by Jet Evaporation.	172.882(a); 172.250; 178.3530(a); 178.3910(a)(4)(i)(*b*) and (b)(2)
ASTM D 388–38 Standard Specifications for Classification of Coals by Rank.	173.25(a)(2)
ASTM D 445–74 Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculations of Dynamic Viscosity).	177.1430(a)(2); 177.1520(d)(5); 178.3740(b)
ASTM D 445–82 Test Method for Kinematic Viscosity of Transparent Opaque Liquids (and the Calculations of Dynamic Viscosity).	178.3740(b)
ASTM D 465–82 Standard Test Methods of Test for Acid Number of Rosin.	178.3870(f)(3)
ASTM D 509–70 (Reapproved 1981) Standard Methods of Sampling and Grading Rosin.	178.3870(f)(1)

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ASTM D 721–56T Tentative Method of Test for Oil Content of Petroleum Waxes.	172.615(a); 175.250(b)(2)
ASTM D 729–81 Standard Specifications for Vinylidene Chloride Molding Compounds.	179.45
ASTM D 938–71 (Reapproved 1980) Standard Method of Test for Congealing Point of Petroleum Waxes, including Petrolatum.	172.615(a); 175.250(b)(1)
ASTM D 968–81 Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester.	177.1590; 177.1650
ASTM D 1218–82 Standard Test Method for Refractive Index and Refractive Dispersion of Hydrocarbon Liquids.	178.2010
ASTM D 1238–82 Standard Method of Measuring Flow Rates of Thermoplastics by Extrusion Plastometer.	176.170(b)(2); 177.1550(d)(2); 177.1570(b)(1)(iii)
ASTM D 1240–82 Standard Method of Test for Rosin Acids in Fatty Acids.	172.862(b)(2)
ASTM D 1243–79 Standard Methods of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers.	175.270(b); 175.300(b)(3)(xxix); 176.170(a)(5); 177.1480(b)(1)(ii); 177.1950(c)(1)(ii); 177.1960(b)(1)(ii); 177.2460(c)(1); 177.1970(c)(1)(ii); 177.1980(c)(1)(ii); 179.45(c)(2)(iv)
ASTM D 1303–55 (Reapproved 1979) Standard Method of Test for Total Chlorine in Vinyl Chloride Polymers and Copolymers.	177.1610(a)
ASTM D 1353–78 Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products.	172.882; 178.3530; 178.3910
ASTM D 1386–78 Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes.	178.3690(b)(2); 178.3770(a)(2) and (b)(2)
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ASTM D 1418–81 Standard Practice for Rubber and Rubber Latices—Nomenclature.	177.2600(c)(4)(i)
ASTM D 1434–82 Standard Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting.	177.1040
ASTM D 1457–56T Test for Thermal Instability Index of Tetrafluoroethylene Homopolymer.	177.1550(d)(3)
ASTM D 1492–78 Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration.	177.1430(a)(3); 178.3740
ASTM D 1500–82 Standard Method of Test for ASTM Color of Petroleum Products (ASTM Color Scale).	178.3620(c)(1)(ii)

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ASTM D 1601–78 Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers.	177.1570(b)(1)(ii)
ASTM D 1646–81 Standard Test Method for Rubber-Viscosity and Volcanization Characteristics (Mooney Viscometer).	177.1520(d)(6)
ASTM D 1747–62 (Reapproved 1978) Standard Test Method for Refractive Index of Viscous Materials and Organosols at Low Shear Rates by Brookfield Viscometer.	178.3870(f)(2)
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ASTM D 1962–67 (Reapproved 1979) Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids.	178.2010(b)
ASTM D 2117–62T Tentative Method of Test for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method.	177.1520(d)(2)(i); 177.1630(d)(4)(v)
ASTM D 2133–66 Specifications for Acetal Resin Injection Molding and Extrusion Materials.	177.2480(c)(4)
ASTM D 2236–70 Standard Method of Test for Dynamic Mechanical Properties of Plastics by Means of a Torsional Pendulum.	177.1810(c)(1)(i)
ASTM D 2161–66 Standard Method of Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity.	178.3740(b)
ASTM D 2503–82 Standard Method of Test for Molecular Weight of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure.	175.300(b)(3)(xxxiii); 176.170(b)(2); 177.1430(a)(1)
ASTM D 2857–70 (Reapproved 1977) Standard Method of Test for Dilute Solution Viscosity of Polymers.	177.1560; 177.2210(b); 177.2440(a)
ASTM D 3536–76 Standard Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by Liquid Exclusion Chromatography (Gel Permeation Chromatography—GPC).	177.1990; 177.2000
ASTM E 28–67 (Reapproved 1982) Tentative Method of Test for Softening Point by Ring and Ball Apparatus.	172.215; 172.280; 176.170(b)(2); 177.1520(d)(2)(ii); 178.3870(b)(5)
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NOTE: The following materials are available through the Food and Drug Administration at the addresses indicated.

Bureau of Foods, Food and Drug Administration
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Journal of the Association of Official Analytical Chemists:	
Changes in Methods: "Glycyrrhizic Acid or Glycyrrhizic Acid Salts in Licorice" Vol. 65, pp. 471–472 (1982).	184.1408
"Flavors and Nonalcoholic Beverages" Vol. 56(5)1281–1283 (1973)	189.110(c)

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"Gas Chromatographic Determination of Safrole and Related Compounds in Nonalcoholic Beverages: Collaborative" Vol. 54(4)900–902 (1971).	189.180(c)
"Gas-Solid Chromatographic Procedures for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents" (Vol. 61, No. 6, pp. 1383–1388).	177.1030(c)(2); 177.1050(e)(4); 180.22(a)
"Headspace Sampling and Gas-Solid Chromatographic Determination of Residual Acrylonitrile in Acrylonitrile Copolymer Solutions" Vol. 65, No. 2, p. 270 (1981).	177.1040
"Oils, Fats, and Waxes" Vol. 50(1)216–218 (1967)	172.860(c)(3)
"Oils, Fats, and Waxes" Vol. 51(2)489–490 (1968)	172.860(c)(3)
"Spectrophotometric Measurements under Specification" Vol. 45, p. 66 (1962).	172.878(a)(3); 172.882(a); 178.3530(a); 178.3620(b)(1)(i)

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Absorptivity Methods "Determination of Softening Point (Drop Method)" Appendix A-2 "Determination of Unsaturation of Resin 1977" Appendix A-3.	178.3610(a)
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"Analysis for Dicholorbenzene in Ryton Polyphenylene Sulfide"	177.2490(a)(3)
Analytical Chemistry, Vol. 49 P. 1090 (1977) "Atomic Absorption Spectrometric Determination of Sub-Part-Per-Million Quantities of Tin in Extracts and Biological Materials with a Graphite Furnace".	178.2650(b)(1)(ii)
Analytical Method for 10% Solution Viscosity of Tyril	177.1040(c)(2)
Analytical Method, "Determination of Free Phenol in Cyclized Rubber Resin".	176.170(b)(2)
Analytical Methods "Determination of Abietic Acid and Dehydroabietic Acid, in Rosins," "Determination of Softening Point of Solid Resins," "Determination of Saponification Number of Rosin Esters," and "Determination of Phenolic Modification of Rosin Derivatives".	178.3870(f)(6)
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Determination of Copolymer Ratio in Vinylidene Chloride/Methyl Acrylate Copolymer.	177.1990
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"Determination of Ethyl Acetate" Test Method U.1, Sept. 29, 1981	172.859
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Exhibit 33B of the report of the NAS/NRC A Comprehensive Survey of Industry on the use of Food Chemicals—GRAS, Sept. 1972.	170.3(n) and (o)
Fishers Johns Method #18 in "Semimiero Qualitative Organic Analysis" Second Ed..	178.3780(b)(1)
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Nonviolative Extractives Method "Determination of Non-Volative Chloroform Soluble Residues in Retort Pouch Water Extractives".	177.1390(c)(3)(i)
Number Average Molecular Weight 2.4 "Osmometry" Method Available from FDA.	177.2470(c)(2)
Phillips Petroleum Company Method VO–65R "Oxygen Flask Combustion-Gravemetric Method For Determination of Sulfur in Organic Compounds" (1965).	177.2490(a)(1)
Phillips Petroleum Company Method 6936–BH "Determination of the Inherent Viscosity of Polyphenylene Sulfide (1969).	177.2490(a)(2)
"Preparation of Extracts"	177.1550(e)
"Protein," NAS in RDA's, NAS Pub. No. 1694, 7th Ed., 1968	172.320(c)(1)
"Qualitative Identification of Kalrez* by Infrared Examination of Pyrolystate".	177.2400(c)
Recommended Dietary Allowances, NAS Publication No. 1694, 7th Ed. (1968).	172.320(c)(1)
Residual Acrylonitrile Monomer Method "Extracted Acrylonitrile Monomer by Differential Pulse Polarography" "Procedure" for the Determination of Molecular Weight of Acrylonitrile/Styrene Copolymers.	177.1020(c)(2); 177.1030(d)(2); 177.1040(c)
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Viscoelastometric method "Direct Reading Viscoelastometric Method for Determining Class Transition Points of Styrene Block Polymers".	177.1810(c)(1)(ii)
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Economic Analysis, Bureau of	15, VIII
Economic Development Administration	13, III
Education, Department of	
Bilingual Education and Minority Languages Affairs, Office of	34, V
Civil Rights, Office for	34, I
Educational Research and Improvement, Office of	34, VII
Elementary and Secondary Education, Office of	34, II
Postsecondary Education, Office of	34, VI
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Vocational and Adult Education, Office of	34, IV
Educational Research and Improvement, Office of	34, VII
Elementary and Secondary Education, Office of	34, II
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Employees Loyalty Board, International Organizations	5, V
Employment and Training Administration	20, V
Employment Standards Administration	20, VI
Endangered Species Committee	50, IV
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Federal Energy Regulatory Commission	18, I
Energy, Office of, Department of Agriculture	7, XXIX
Engineers, Corps of	33, II; 36, III
Engraving and Printing, Bureau of	31, VI
Environmental Protection Agency	40, I; 41, 115; 48, 15
Environmental Quality, Office of (Agriculture Department)	7, XXXI
Equal Employment Opportunity Commission	29, XIV
Equal Opportunity, Office of Assistant Secretary for	24, I
Executive Office of the President	3, I
Administration, Office of	5, XV
Export-Import Bank of the United States	12, IV
Family Assistance, Office of	45, II
Farm Credit Administration	12, VI
Farmers Home Administration	7, XVIII
Federal Acquisition Regulation	48, 1
Federal Aviation Administration	14, I
Federal Claims Collection Standards	4, II
Federal Communications Commission	47, I
Federal Contract Compliance Programs, Office of	41, 60
Federal Crop Insurance Corporation	7, IV
Federal Deposit Insurance Corporation	12, III
Federal Election Commission	11, I
Federal Emergency Management Agency	44, I; 48, 44
Federal Energy Regulatory Commission	18, I
Federal Financial Institutions Examination Council	12, XI
Federal Financing Bank	12, VIII
Federal Grain Inspection Service	7, VIII
Federal Highway Administration	23, I, II; 49, III
Federal Home Loan Bank Board	12, V
Federal Home Loan Mortgage Corporation	1, IV
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Federal Inspector for the Alaska Natural Gas Transportation System, Office of	10, XV
Federal Labor Relations Authority, and General Counsel of the Federal Labor Relations Authority	5, XIV; 22, XIV
Federal Law Enforcement Training Center	31, VII
Federal Maritime Commission	46, IV
Federal Mediation and Conciliation Service	29, XII

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Federal Pay, Advisory Committee on	5, IV
Federal Prison Industries	28, III
Federal Property Management Regulations	41, 101
Federal Property Management Regulations System	41, Subtitle C
Federal Railroad Administration	49, II
Federal Register, Administrative Committee of	1, I
Federal Register, Office of	1, II
Federal Reserve System	12, II
Federal Retirement Thrift Investment Board	5, VI
Federal Service Impasses Panel	5, XIV
Federal Trade Commission	16, I
Fine Arts Commission	45, XXI
Fiscal Service	31, II
Fish and Wildlife Service, United States	50, I, IV
Fishery Conservation and Management	50, VI
Fishing and Whaling, International Regulatory Agencies	50, III
Food and Drug Administration	21, I
Food and Nutrition Service	7, II
Food Safety and Inspection Service	9, III
Foreign Agricultural Service	7, XV
Foreign Assets Control, Office of	31, V
Foreign Claims Settlement Commission of United States	45, V
Foreign Economic Development Service	7, XXI
Foreign Service Grievance Board	22, IX
Foreign Service Impasse Disputes Panel	22, XIV
Foreign Service Labor Relations Board	22, XIV
Foreign-Trade Zones Board	15, IV
Forest Service	36, II
General Accounting Office	4, I, II, III
General Sales Manager, Office of	7, XXV
General Services Administration	
Contract Appeals Board	48, 61
Federal Acquisition Regulation	48, 5
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Government National Mortgage Association	24, III
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Harry S Truman Scholarship Foundation	45, XVIII
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Child Support Enforcement, Office of	45, III
Community Services, Office of	45, X
Family Assistance, Office of	45, II
Federal Acquisition Regulation	48, 3
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Health Care Financing Administration	42, IV
Human Development Services Office	45, XIII
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Refugee Resettlement, Office of	45, IV
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Health Care Financing Administration	42, IV
Housing and Urban Development, Department of	
Community Planning and Development, Office of Assistant Secretary for	24, V, VI
Equal Opportunity, Office of Assistant Secretary for	24, I
Federal Acquisition Regulation	48, 24
Government National Mortgage Association	24, III
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Inspector General, Office of	24, XII
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Agency	CFR Title, Subtitle or Chapter
Public and Indian Housing, Office of Assistant Secretary for	24, IX
Secretary, Office of	24, Subtitle A, VII
Solar Energy and Energy Conservation Bank	24, XI
Housing—Federal Housing Commissioner, Office of Assistant Secretary for	24, II, VIII, X, XX
Human Development Services Office	45, XIII
Immigration and Naturalization Service	8, I
Indian Affairs, Bureau of	25, I
Indian Arts and Crafts Board	25, II
Industrial Economics, Bureau of, Commerce Department	15, VI
Information Agency, United States	22, V; 48, 19
Information Resources Management, Office of, Agriculture Department	7, XXVII
Information Security Oversight Office	32, XX
Inspector General, Office of, Agriculture Department	7, XXVI
Inspector General, Office of, Health and Human Services Department	42, V
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Intergovernmental Relations, Advisory Commission on	5, VII
Interior Department	
Endangered Species Committee	50, IV
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Fish and Wildlife Service, United States	50, I, IV
Geological Survey	30, IV
Indian Affairs, Bureau of	25, I
Indian Arts and Crafts Board	25, II
Land Management Bureau	43, II
Minerals Management Service	30, II
Mines, Bureau of	30, VI
National Park Service	36, I
Reclamation Bureau	43, I
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Surface Mining and Reclamation Appeals, Board of	30, III
Surface Mining Reclamation and Enforcement, Office of	30, VII
United States Fish and Wildlife Service	50, I, IV
Internal Revenue Service	26, I
International Boundary and Water Commission, United States and Mexico	22, XI
International Cooperation and Development Office	7, XXII
International Development, Agency for	22, II
International Development Cooperation Agency	22, XII
International Development, Agency for	22, II
International Joint Commission, United States and Canada	22, IV
International Organizations Employees Loyalty Board	5, V
International Regulatory Agencies (Fishing and Whaling)	50, III
International Trade Administration	15, III; 19, III
International Trade Commission, United States	19, II
Interstate Commerce Commission	49, X
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Joint Board for the Enrollment of Actuaries	20, VIII
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Labor Department	
Benefits Review Board	20, VII

Agency	CFR Title, Subtitle or Chapter
Employees' Compensation Appeals Board	20, IV
Employment and Training Administration	20, V
Employment Standards Administration	20, VI
Federal Acquisition Regulation	48, 29
Federal Contract Compliance Programs, Office of	41, 60
Federal Procurement Regulations System	41, 50
Labor-Management Relations and Cooperative Programs, Bureau of	29, II
Labor-Management Standards, Office of	29, IV
Mine Safety and Health Administration	30, I
Occupational Safety and Health Administration	29, XVII
Pension and Welfare Benefits Administration	29, XXV
Public Contracts	41, 50
Secretary of Labor, Office of	29, Subtitle A
Veterans Employment and Training, Office of the Assistant Secretary for	41, 61
Wage and Hour Division	29, V
Workers' Compensation Programs, Office of	20, I
Labor-Management Relations and Cooperative Programs, Bureau of	29, II
Labor-Management Standards, Office of	29, IV
Land Management, Bureau of	43, II
Legal Services Corporation	45, XVI
Library of Congress	36, VII
Copyright Office	37, II
Management and Budget, Office of	5, III
Marine Mammal Commission	50, V
Maritime Administration	46, II
Merit Systems Protection Board	5, II
Micronesian Status Negotiations, Office for	32, XXVII
Mine Safety and Health Administration	30, I
Minerals Management Service	30, II
Mines, Bureau of	30, VI
Minority Business Development Agency	15, XIV
Miscellaneous Agencies	1, IV
Monetary Offices	31, I
Mortgage Insurance and Loan Programs Under the Emergency Homeowners' Relief Act, Department of Housing and Urban Development	24, XV
National Aeronautics and Space Administration	14, V; 48, 18
National Agricultural Statistics Service	7, XXXVI
National Archives and Records Administration	36, XII
National Bureau of Standards	15, II
National Capital Planning Commission	1, IV
National Commission on Libraries and Information Science	45, XVII
National Credit Union Administration	12, VII
National Foundation on the Arts and the Humanities	45, XI
National Highway Traffic Safety Administration	23, II, III; 49, V
National Labor Relations Board	29, I
National Marine Fisheries Service	50, II, IV
National Mediation Board	29, X
National Oceanic and Atmospheric Administration	15, IX; 50, II, III, IV, VI
National Park Service	36, I
National Railroad Adjustment Board	29, III
National Railroad Passenger Corporation (AMTRAK)	49, VII
National Science Foundation	45, VI; 48,25
National Security Council	32, XXI
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National Telecommunications and Information Administration	15, XXIII
National Transportation Safety Board	49, VIII
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Nuclear Regulatory Commission	10, I
Occupational Safety and Health Administration	29, XVII
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Panama Canal Regulations	35, I
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Pennsylvania Avenue Development Corporation	36, IX
Pension and Welfare Benefits Administration, Department of Labor	29, XXV
Pension Benefit Guaranty Corporation	29, XXVI
Personnel Management, Office of	5, I; 45, VIII; 48, 17
Postal Rate Commission	39, III
Postal Service, United States	39, I
Postsecondary Education, Office of	34, VI
President's Commission on White House Fellowships	1, IV
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Productivity, Technology and Innovation, Assistant Secretary (Commerce)	37, IV
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Public Contracts, Department of Labor	41, 50
Public Health Service	42, I
Railroad Retirement Board	20, II
Railway Association, United States	49, IX
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Regional Action Planning Commissions	13, V
Research and Special Programs Administration	49, I
Rural Electrification Administration	7, XVII
Rural Telephone Bank	7, XVI
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Saint Lawrence Seaway Development Corporation	33, IV
Science and Technology Policy, Office of	32, XXIV
Science and Technology Policy, Office of, and National Security Council	47, II
Secret Service	31, IV
Securities and Exchange Commission	17, II
Selective Service System	32, XVI
Small Business Administration	13, I; 48, 22
Smithsonian Institution	36, V
Social Security Administration	20, III; 45, IV
Soil Conservation Service	7, VI
Solar Energy and Energy Conservation Bank, Department of HUD	24, XI
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Special Education and Rehabilitative Services, Office of	34, III
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Trade Representative, United States, Office of	15, XX
Transportation, Department of	44, IV
Coast Guard	33, I; 46, I, III; 49, IV
Commercial Space Transportation, Office of	14, III
Federal Acquisition Regulation	48, 12
Federal Aviation Administration	14, I
Federal Highway Administration	23, I, II; 49, III
Federal Railroad Administration	49, II
Maritime Administration	46, II
National Highway Traffic Safety Administration	23, II, III; 49, V
Research and Special Programs Administration	49, I
Saint Lawrence Seaway Development Corporation	33, IV
Secretary of Transportation, Office of	14, II; 49, Subtitle A

Agency	CFR Title, Subtitle or Chapter
Urban Mass Transportation Administration	49, VI
Transportation, Office of, Department of Agriculture	7, XXXIII
Travel Service, United States	15, XII
Treasury Department	
Alcohol, Tobacco and Firearms, Bureau of	27, I
Comptroller of the Currency	12, I
Customs Service, United States	19, I
Engraving and Printing, Bureau of	31, VI
Federal Acquisition Regulation	48, 10
Federal Law Enforcement Training Center	31, VII
Fiscal Service	31, II
Foreign Assets Control, Office of	31, V
Internal Revenue Service	26, I
Monetary Offices	31, I
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Secretary of the Treasury, Office of	31, Subtitle A
United States Customs Service	19, I
Truman, Harry S, Scholarship Foundation	45, XVIII
United States and Canada, International Joint Commission	22, IV
United States Arms Control and Disarmament Agency	22, VI
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United States Information Agency	22, V; 48, 19
United States International Development Cooperation Agency	22, XII
United States International Trade Commission	19, II
United States Postal Service	39, I
United States Railway Association	49, IX
United States Soldiers' and Airmen's Home	5, XI
United States Trade Representative, Office of	15, XX
United States Travel Service	15, XII
Urban Mass Transportation Administration	49, VI
Veterans Administration	38, I; 48, 8
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Vocational and Adult Education, Office of	34, IV
Wage and Hour Division	29, V
Water Resources Council	18, VI
Workers' Compensation Programs, Office of	20, I

Redesignation Table

At 42 FR 14302, Mar. 15, 1977 (Recodification Docket No. 15), certain general regulations applicable to human food formerly under Subchapter A were incorporated into reorganized Subchapter B and republished.

The following table shows the relationship of the CFR section numbers formerly under Subchapter A and those sections being redesignated under the reorganized Subchapter B and under Subchapter E. This conversion table includes all changes made by FDA recodification document number 14 (41 FR 38618, Sept. 10, 1976) and recodification document number 15.

Old section	New human section	New animal section [1]
85.1	197.810	NA
85.2	197.812	NA
85.3	197.820	NA
85.4	197.825	NA
85.5	197.829	NA
85.6	197.830	NA
85.7	197.840	NA
85.8	197.850	NA
85.9	197.855	NA
85.10	197.860	NA
85.11	197.870	NA
85.12	197.880	NA
85.13	197.885	NA
85.14	197.815	NA
85.16	197.310	NA
85.17	197.312	NA
85.18	197.320	NA
85.19	197.325	NA
85.20	197.329	NA
85.21	197.330	NA
85.22	197.340	NA
85.23	197.350	NA
85.24	197.355	NA
85.25	197.360	NA
85.26	197.370	NA
85.27	197.380	NA
85.28	197.385	NA
85.29	197.315	NA
121.1	170.3	[2] 570.3
121.2	170.19	570.19
121.3	170.30	570.30
121.4	170.18	570.18
121.5	170.22	570.22
121.6	170.20	570.20
121.8	170.10	NA
121.10	170.45	NA
121.11	170.6	570.6
121.12	170.50	NA
121.13	170.60	NA
121.14	181.5	NA
121.40	170.35	570.35
121.41	170.38	570.38
121. 1 except (k) and (l)	171.1	571.1
121.51 (k) and (l)	171.100	571.100
121.52	171.7	571.7
121.53	171.6	571.6
121.54	171.102	571.102
121.55	171.110	571.110
121.72	170.15	570.15
121.74	171.130	571.130
121.75	170.17	570.17
121.101 except table in (d) and (e) through (i)	182.1	582.1
121.101(d)	182.1005	582.1005
	182.1009	582.1009
	182.1033	582.1033
	182.1045	NA
	182.1047	NA
	182.1057	582.1057
	182.1061	582.1061
	182.1069	582.1069
	182.1073	582.1073
	182.1077	582.1077
	182.1087	582.1087
	182.1091	582.1001
	182.1005	582.1005
	182.1099	582.1099
	182.1125	582.1125
	182.1127	582.1127
	182.1129	582.1129
	128.1131	582.1131
	182.1135	582.1135
	182.1137	582.1137
	182.1139	582.1139
	182.1141	582.1141
	182.1143	582.1143
	182.1155	582.1155
	182.1165	582.1165
	182.1180	NA
	182.1191	582.1911
	182.1193	582.1193
	182.1195	582.1195
	182.1199	582.1199
	182.1205	582.1205
	182.1207	582.1207
	182.1210	582.1210
	182.1217	582.1217
	182.1235	582.1235
	182.1240	582.1240
	182.1275	582.1275

Old section	New human section	New animal section [1]
	182.1295	NA
	182.1320	582.1320
	182.1324	582.1324
	182.1355	582.1355
	182.1366	582.1366
	182.1400	582.1400
	182.1425	582.1425
	182.1428	582.1428
	182.1431	582.1431
	182.1440	NA
	182.1480	582.1480
	182.1500	582.1500
	182.1516	582.1516
	182.1540	582.1540
	182.1545	NA
	182.1585	582.1585
	182.1613	582.1613
	182.1619	582.1619
	182.1625	582.1625
	182.1631	582.1631
	182.1643	582.1643
	182.1655	582.1655
	182.1666	582.1666
	182.1685	582.1685
	182.1711	582.1711
	182.1721	582.1721
	182.1736	582.1736
	182.1742	582.1742
	182.1745	582.1745
	182.1748	582.1748
	182.1751	582.1751
	182.1763	582.1763
	182.1775	582.1775
	182.1778	582.1778
	182.1781	582.1781
	182.1792	582.1792
	182.1804	582.1804
	182.1810	582.1810
	182.1901	582.1901
	182.1911	NA
	182.1973	582.1973
	182.1975	582.1975
	182.1978	582.1978
	182.2122	582.2122
	182.2227	582.2227
	182.2437	582.2437
	182.2727	582.2727
	182.2729	582.2729
	182.2906	582.2906
	182.3013	582.3013
	[1] NA	582.3021
	182.3025	NA
	182.3041	582.3041
	182.3081	582.3081
	182.3089	582.3089
	182.3109	582.3109
	182.3149	582.3149
	182.3169	582.3169
	182.3173	582.3173
	182.3189	582.3189
	182.3221	582.3221
	182.3225	582.3225
	182.3280	582.3280
	182.3336	582.3336
	[1] NA	582.3490
	182.3616	582.3616
	182.3637	582.3637
	182.3640	582.3640
	[1] NA	582.3660
	[1] NA	582.3670
	182.3731	582.3731

Old section	New human section	New animal section [1]
	[3] NA	582.3733
	182.3739	582.3739
	182.3766	582.3766
	182.3784	582.3784
	182.3795	582.3795
	182.3798	582.3798
	182.3845	582.3845
	182.3862	582.3862
	182.3890	582.3890
	182.4029	NA
	182.4037	NA
	182.4053	NA
	182.4101	582.4101
	182.4105	NA
	182.4505	582.4505
	182.4521	582.4521
	182.4560	NA
	182.4666	582.4666
	182.5013	582.5013
	NA	582.5017
	NA	582.5049
	182.5065	582.5065
	NA	582.5118
	NA	582.5145
	182.5159	582.5159
	182.5191	582.5191
	182.5195	582.5195
	182.5201	582.5201
	182.5210	582.5210
	182.5212	582.5212
	182.5217	582.5217
	182.5223	582.5223
	182.5230	582.5230
	182.5245	582.5245
	182.5250	582.5250
	182.5252	582.5252
	182.5260	582.5260
	182.5265	NA
	[3] NA	582.5271
	NA	582.5273
	182.5301	582.5301
	182.5304	582.5304
	182.5306	582.5306
	182.5308	582.5308
	182.5311	582.5311
	182.5315	582.5315
	NA	582.5361
	182.5370	582.5370
	182.5375	582.5375
	NA	582.5381
	NA	582.5406
	NA	582.5411
	182.5431	582.5431
	182.5434	582.5434
	182.5443	582.5443
	182.5446	582.5446
	182.5449	582.5449
	182.5452	582.5452
	182.5455	582.5455
	182.5458	582.5458
	182.5461	582.5461
	182.5464	582.5464
	NA	582.5470
	NA	582.5475
	NA	582.5477
	182.5530	582.5530
	182.5535	582.5535
	182.5580	582.5580
	NA	582.5590
	182.5622	582.5622
	182.5628	582.5628

Redesignation Table

Old section	New human section	New animal section[1]
	182.5634	582.5634
	NA	582.5650
	182.5676	582.5676
	182.5695	582.5695
	182.5697	582.5697
	NA	582.5701
	182.5772	582.5772
	182.5778	582.5778
	NA	582.5835
	182.5875	582.5875
	182.5878	582.5878
	NA	582.5881
	182.5890	582.5890
	182.5892	582.5892
	NA	582.5915
	NA	582.5920
	NA	582.5925
	182.5930	582.5930
	182.5933	582.5933
	182.5936	582.5936
	182.5945	582.5945
	182.5950	582.5950
	182.5953	582.5953
	182.5985	582.5985
	182.5988	582.5988
	182.5991	582.5991
	182.5994	582.5994
	182.5997	582.5997
	182.6033	582.6033
	182.6085	582.6085
	182.6099	582.6099
	182.6185	582.6185
	182.6193	582.6193
	182.6195	582.6195
	182.6197	582.6197
	182.6199	582.6199
	182.6203	582.6203
	182.6215	582.6215
	182.6219	582.6219
	182.6285	582.6285
	182.6290	582.6290
	182.6386	582.6386
	182.6511	582.6511
	182.6625	582.6625
	182.6751	582.6751
	182.6754	582.6754
	182.6757	582.6757
	182.6760	582.6760
	182.6769	582.6769
	182.6778	582.6778
	182.6787	582.6787
	182.6789	582.6789
	182.6801	582.6801
	182.6804	582.6645
	182.6807	582.6807
	182.6810	582.6810
	182.6851	582.6851
	182.7115	582.7115
	182.7133	582.7133
	182.7187	582.7187
	182.7255	582.7255
	[3] NA	582.7330
	[3] NA	582.7333
	[3] NA	582.7339
	[3] NA	582.7343
	[3] NA	582.7349
	[3] NA	582.7351
	182.7610	582.7610
	182.7724	582.7724
121.101(e)(1)	182.10	582.10
121.101(e)(2)	182.20	582.20
121.101(e)(3)	182.30	582.30
121.101(e)(4)	182.40	582.40
121.101(e)(5)	182.50	582.50
121.101(f)	NA	582.80
121.101(g)	182.60	582.60
121.101(h)	182.90	NA
121.101(i)	182.70	NA
121.102	182.99	582.99
121.104 except (g)	184.1	NA
121.104(g)(1)	184.1490	NA
121.104(g)(2)	184.1670	NA
121.104(g)(4)	184.1835	NA
121.104(g)(5)	184.1343	NA
121.104(g)(6)	184.1021	NA
121.104(g)(7)	184.1733	NA
121.104(g)(8)	184.1317	NA
121.104(g)(13)	184.1282	NA
121.104(g)(17)	184.1333	NA
121.104(g)(18)	184.1351	NA
121.104(g)(19)	184.1330	NA
121.104(g)(20)	184.1349	NA
121.104(g)(21)	184.1699	NA
121.104(g)(22)	184.1271	NA
121.104(g)(23)	184.1272	NA
121.104(g)(24)	184.1293	NA
121.104(g)(25)	184.1983	NA
121.104(g)(26)	184.1660	NA
121.104(g)(27)	184.1339	NA
121.105 (except (f))	186.1	NA
121.105(f)(1)	186.1343	NA
121.105(f)(2)	186.1339	NA
121.105(f)(3)	186.1673	NA
121.105(f)(4)	186.1330	NA
121.106 except (d) and (e).	189.1	NA
121.106(d)(1)	189.110	NA
121.106(d)(2)	189.145	NA
121.106(d)(3)	189.175	NA
121.106(d)(4)	189.130	NA
121.106(d)(5)	189.135	NA
121.106(d)(6)	189.150	NA
121.106(d)(7)	189.155	NA
121.106(d)(8)	189.190	NA
121.106(d)(9)	189.120	NA
121.106(d)(10)	189.165	NA
121.106(d)(11)	189.140	NA
121.106(e)(1)	189.220	NA
121.106(e)(2)	189.280	NA
121.106(e)(3)	189.250	NA
121.201	NA	573.400
121.202	NA	573.380
121.203	NA	573.820
121.206	NA	573.500
121.209	NA	573.180
121.219	NA	573.480
121.222	NA	573.1000
121.223	NA	573.700
121.224	NA	573.640
121.229	NA	573.940
121.230	NA	573.420
121.231	NA	573.300
121.234	NA	573.600
121.235	NA	573.880
121.236	NA	573.840
121.239	NA	573.780
121.242	NA	573.660
121.246	NA	573.680
121.247	NA	573.580
121.250	NA	573.260
121.261	NA	573.720
121.265	NA	573.320

Old section	New human section	New animal section[1]
121.271	NA	573.360
121.272	NA	573.960
121.273	NA	573.900
121.275	NA	573.520
121.277	NA	573.740
121.282	NA	573.560
121.283	NA	573.980
121.284	NA	573.1020
121.285	NA	573.160
121.286	NA	573.620
121.288	NA	573.120
121.295	NA	573.760
121.298	NA	573.440
121.301	NA	573.540
121.302	NA	573.200
121.306	NA	573.280
121.307	NA	573.880
121.313	NA	573.240
121.319	NA	573.140
121.320	NA	573.800
121.322	NA	573.340
121.325	NA	573.920
121.328	NA	573.220
121.329	NA	573.460
121.1000	172.5	NA
121.1001	172.140	NA
121.1002	172.320	NA
121.1004	172.852	NA
121.1008	172.838	NA
121.1009	172.840	NA
121.1010	172.725	NA
121.1012	172.822	NA
121.1015	172.858	NA
121.1016	172.818	NA
121.1017	172.120	NA
121.1018	172.828	NA
121.1019	172.894	NA
121.1021	172.874	NA
121.1023	172.802	NA
121.1027	172.814	NA
121.1028	172.876	NA
121.1029	172.842	NA
121.1030	172.836	NA
121.1031	172.892	NA
121.1032	172.490	NA
121.1034	172.115	NA
121.1035	172.110	NA
121.1036	172.832	NA
121.1037	172.330	NA
121.1039	173.255	NA
121.1040	173.230	NA
121.1041	173.290	NA
121.1042	173.210	NA
121.1043	173.240	NA
121.1044	173.250	NA
121.1045	173.270	NA
121.1047	172.844	NA
121.1048	172.848	NA
121.1050	172.215	NA
121.1056	172.135	NA
121.1058	172.480	NA
121.1059	172.615	NA
121.1060	172.350	NA
121.1063	172.170	NA
121.1064	172.175	NA
121.1065	173.360	NA
121.1066	172.620	NA
121.1067	172.626	NA
121.1068	172.655	NA
121.1069	172.660	NA
121.1070	172.860	NA
121.1071	172.863	NA
121.1073	172.375	NA
121.1077	172.280	NA
121.1080	172.755	NA
121.1081	172.575	NA
121.1082	172.560	NA
121.1084	172.735	NA
121.1085	172.806	NA
121.1086	172.585	NA
121.1087	172.868	NA
121.1088	173.310	NA
121.1089	172.130	NA
121.1090	172.535	NA
121.1091	172.315	NA
121.1092	173.5	NA
121.1095	172.315	NA
121.1097	172.580	NA
121.1098	172.890	NA
121.1099	172.340	NA
121.1100	172.370	NA
121.1101	172.275	NA
121.1102	172.715	NA
121.1105	172.235	NA
121.1109	172.530	NA
121.1110	173.50	NA
121.1111	172.866	NA
121.1112	172.872	NA
121.1113	172.856	NA
121.1114	172.395	NA
121.1116	172.190	NA
121.1119	172.255	NA
121.1120	172.854	NA
121.1122	172.850	NA
121.1123	172.335	NA
121.1125	172.896	NA
121.1130	172.350	NA
121.1132	172.160	NA
121.1134	172.345	NA
121.1135	172.410	NA
121.1136	172.775	NA
121.1137	172.810	NA
121.1139	173.55	NA
121.1141	172.310	NA
121.1142	172.260	NA
121.1143	172.878	NA
121.1148	173.25	NA
121.1149	172.335	NA
121.1151	172.816	NA
121.1154	172.882	NA
121.1155	173.320	NA
121.1156	172.886	NA
121.1160	172.870	NA
121.1161	172.770	NA
121.1162	172.720	NA
121.1163	172.510	NA
121.1164	172.515	NA
121.1165	173.130	NA
121.1166	172.880	NA
121.1170	173.135	NA
121.1171	173.385	NA
121.1174	172.610	NA
121.1176	173.220	NA
121.1179	172.210	NA
121.1180	173.20	NA
121.1181	173.345	NA
121.1182	172.884	NA
121.1183	172.826	NA
121.1185	172.820	NA
121.1186	172.145	NA
121.1190	172.430	NA
121.1192	173.10	NA

Redesignation Table

Old section	New human section	New animal section [1]
121.1193	172.623	NA
121.1194	172.730	NA
121.1195	172.830	NA
121.1197	172.765	NA
121.1198	172.824	NA
121.1199	173.150	NA
121.1202	172.385	NA
121.1203	172.250	NA
121.1208	172.150	NA
121.1209	173.355	NA
121.1211	172.846	NA
121.1213	172.180	NA
121.1219	172.230	NA
121.1221	172.834	NA
121.1224	172.695	NA
121.1225	172.710	NA
121.1228	172.275	NA
121.1229	172.520	NA
121.1230	172.177	NA
121.1233	173.120	NA
121.1235	172.808	NA
121.1237	172.862	NA
121.1238	172.864	NA
121.1239	172.888	NA
121.1244	172.185	NA
121.1246	173.40	NA
121.1250	172.590	NA
121.1255	173.160	NA
121.1257	172.812	NA
121.1258	172.804	NA
121.1259	173.165	NA
121.1260	173.145	NA
121.1262	172.898	NA
121.1263	172.325	NA
121.1265	173.110	NA
121.1266	172.225	NA
121.1267	173.280	NA
121.1268	172.712	NA
121.2000	181.1	NA
121.2005 (introductory text)	181.22	NA
121.2005(a)	181.24	NA
121.2005(b)	181.23	NA
121.2005(c)	181.25	NA
121.2005(d)	181.26	NA
121.2005(e)	181.27	NA
121.2005(f)	181.28	NA
121.2005(g)	181.29	NA
121.2005(h)	181.30	NA
121.2010	181.32	NA
121.2500	174.5	NA
121.2501	177.1520	NA
121.2502	177.1500	NA
121.2503	178.3930	NA
121.2505	176.300	NA
121.2506	178.3520	NA
121.2507	177.1200	NA
121.2508	178.2550	NA
121.2509	178.3860	NA
121.2510	177.1640	NA
121.2511	178.3740	NA
121.2512	176.110	NA
121.2513	178.3750	NA
121.2514	175.300	NA
121.2515	176.150	NA
121.2516	176.320	NA
121.2517	177.1620	NA
121.2518	176.160	NA
121.2519	176.210	NA
121.2520	175.105	NA
121.2521	177.1980	NA
121.2522	177.1680	NA
121.2523	177.1380	NA
121.2524	177.1630	NA
121.2525	175.210	NA
121.2526	176.170	NA
121.2527	178.3130	NA
121.2528	177.1340	NA
121.2529	176.230	NA
121.2530	178.3850	NA
121.2531	178.3910	NA
121.2532	177.1610	NA
121.2533	177.1240	NA
121.2534	178.3120	NA
121.2535	177.2800	NA
121.2536	177.2260	NA
121.2537	176.130	NA
121.2538	176.120	NA
121.2539	176.350	NA
121.2540	175.350	NA
121.2541	178.3400	NA
121.2543	179.45	NA
121.2544	178.3950	NA
121.2545	177.1850	NA
121.2546	176.260	NA
121.2547	178.1010	NA
121.2548	175.390	NA
121.2549	177.1460	NA
121.2550	177.1210	NA
121.2551	178.3300	NA
121.2552	178.3500	NA
121.2553	178.3570	NA
121.2554	177.1320	NA
121.2555	177.1550	NA
121.2556	178.8800	NA
121.2557	176.200	NA
121.2558	178.3530	NA
121.2559	175.380	NA
121.2560	176.250	NA
121.2561	178.3450	NA
121.2562	177.2600	NA
121.2563	178.3970	NA
121.2564	177.1310	NA
121.2565	178.3290	NA
121.2566	178.2010	NA
121.2567	177.1400	NA
121.2569	175.320	NA
121.2570	177.1350	NA
121.2571	176.180	NA
121.2572	177.1650	NA
121.2573	178.3730	NA
121.2574	177.1580	NA
121.2575	175.250	NA
121.2576	177.2420	NA
121.2577	175.125	NA
121.2578	175.230	NA
121.2579	177.1440	NA
121.2580	177.1600	NA
121.2581	177.2430	NA
121.2582	177.1330	NA
121.2583	178.3010	NA
121.2584	177.2710	NA
121.2585	177.2280	NA
121.2586	178.3710	NA
121.2587	177.2410	NA
121.2588	178.3700	NA
121.2589	178.3620	NA
121.2590	177.1420	NA
121.2591	177.1010	NA
121.2592	178.3870	NA
121.2593	177.2510	NA
121.2594	178.3650	NA

Old section	New human section	New animal section [1]
121.2595	177.1900	NA
121.2596	178.3900	NA
121.2597	178.3790	NA
121.2598	177.1670	NA
121.2599	175.360	NA
121.2600	175.365	NA
121.2601	175.260	NA
121.2602	176.2650	NA
121.2603	177.2460	NA
121.2604	178.3600	NA
121.2605	178.3770	NA
121.2606	178.3940	NA
121.2607	178.3760	NA
121.2608	177.1970	NA
121.2609	177.1950	NA
121.2610	177.1430	NA
121.2611	177.1830	NA
121.2612	175.270	NA
121.2613	177.2500	NA
121.2614	177.1480	NA
121.2615	178.3610	NA
121.2616	178.3480	NA
121.2617	177.1570	NA
121.2618	178.3720	NA
121.2619	177.1380	NA
121.2620	178.3280	NA
121.2621	177.2490	NA
121.2622	177.1810	NA
121.2623	177.1980	NA
121.2624	178.3550	NA
121.2625	177.1050	NA
121.2626	177.1820	NA
121.2627	177.1030	NA
121.2628	177.2450	NA
121.2629	177.1040	NA
121.2630	178.3780	NA
121.2631	177.2250	NA
121.2632	177.1590	NA
121.2633	177.1020	NA
121.2634	177.2910	NA
121.2635	177.1660	NA
121.2636	177.2210	NA
121.2637	177.2470	NA
1121.2638	178.2480	NA
1121.3001	179.21	NA
1121.3003	179.22	NA
1211.3006	179.39	NA
1211.3007	179.24	NA
121.3008	179.30	NA
121.4000	180.1	NA
121.4001	180.37	NA
121.4004	180.30	NA
121.4005	180.25	NA
122.4010	180.22	NA

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[1] The text of the animal food regulations listed in this column are set forth in the fourteenth recodification document published in the FEDERAL REGISTER of Sept. 10, 1976 (41 FR 38618).

[2] Section 570.3 does not include pars. (n) and (o) of former § 121.1.

[3] The procedure for listing substances when affirmed as GRAS is to eliminate them from listing in Part 182 (formerly § 121.101(d)). For substances affirmed as GRAS in human food, see Parts 184 and/or 186. For all GRAS substances in animal food, see Part 582 (published in the FEDERAL REGISTER of September 10, 1976 (41 FR 38618)).

List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1973, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For the period before January 1, 1973, see the "List of CFR Sections Affected, 1949-1963 and 1964-1972," published in three separate volumes.

1973

(Regulations published from January 1, 1973 through March 31, 1973)

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Chapter I	
191.9 (a)(3) revised	4666
191.9a (b) added, eff. 9-3-73	6141
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1973–1974

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Chapter I	
170 Redesignated as § 700.3 and Part 710	Δ10054
172 Redesignated as § 700.3 and Part 720	Δ10054
174 Added	28915
174 Effective date changed	Δ9185
Redesignated as § 700.3 and Part 730	Δ10054
174.5 (a)(9) corrected	34998
191 Removed; provisions transferred to 16 CFR Part 1500	27012
191.4 Added	11079
191.9 (a)(3) revised	10444
191b Removed; provisions transferred to 16 CFR Part 1505	27012

NOTE: Symbol (Δ) refers to 1974 page numbers.

1974–1975

(No regulations published from April 1, 1974 through March 31, 1975)

1975–1976

(No regulations published from April 1, 1975 through March 31, 1976)

1976–1977

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170 Redesignated from 121.1 through 121.41 and revised	*14483
170.15 (b) amended	*15673
170.35 (c)(1) amended	*15673
170.38 (b)(1) amended	*15673
171 Redesignated from 121.1000 through 121.1268 and revised	*14489
171.1 (c), (h)(1) (ii), (iv), (v), (2), and (3) amended	*15674
171.6 Amended	*15674
171.110 Amended	*15674
171.130 (a) amended	*15674
172 Redesignated from 121.1000 through 121.1268 and revised	*14491
173 Redesignated from 121.1000 through 121.1268 and revised	*14526

NOTE: Symbol (*) refers to 1977 page numbers.

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174 Redesignated from 121.2500 and revised ... *14534
175 Redesignated from 121.2501 through 121.2638 and revised ... *14534
175.125 (a)(3) amended ... *15674
176 Redesignated from 121.2501 through 121.2638 and revised ... *14554
177 Redesignated from 121.2501 through 121.2638 and revised ... *14572
178 Redesignated from 121.2501 through 121.2638 and revised ... *14609
179 Redesignated from 121.3001 through 121.3008 and revised ... *14635
180 Redesignated from 121.4000 through 121.4010 and revised ... *14636
180.1 (c) amended ... *15674
181 Redesignated from 121.14 and 121.2000 through 121.2010 revised ... *14638
182 Redesignated from 121.101 through 121.102 and revised ... *14640
184 Redesignated from 121.104 and revised ... *14653
186 Redesignated from 121.105 and revised ... *14658
189 Redesignated from 121.106 and revised ... *14659
193 Redesignated from 123 ... 26568
193.10 Added ... 28952
193.235 Added ... 32888
193.284 Revised ... 31530
193.301 Revised ... 47231
Corrected ... 51009
197 Redesignated from Part 85 and revised ... *14661

1977–1978

(Regulations published from April 1, 1977 through March 31, 1978)

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172.320 (a), (b), and (c)(4) corrected ... 56728
172.515 (b) amended ... 23148

NOTE: Symbol (*) refers to 1977 page numbers.

NOTE: Symbol (†) refers to 1978 page numbers.

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172.834 (c) amended ... 37973
172.836 (c)(1) revised ... †2871
172.838 (c)(3) revised ... †2871
172.840 (c)(9) revised ... †2871
172.842 (c)(1) revised ... †2871
172.892 (e) amended ... †11697
173.150 Heading corrected ... 56728
173.315 (a)(3) added ... 29856
(a)(3) table revised ... 32229
173.340 (a)(3) amended ... †2872
173.345 (b) and (c)(1)(i) revised; eff. 2-15-78 and 4-15-79 in part ... †11317
175.105 (c) table corrected ... 56728
(c)(5) amended ... 59495
(c)(5) amended ... †2873
175.300 (b)(3)(xii) and (xiii) revised ... 18610
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(b)(3)(xx) amended ... 44222
(b)(3)(xx) corrected ... 61254
(b)(3)(xxxi) amended; (b)(3)(xx) corrected ... †2873
(b)(3)(xx) amended ... †6216
(b)(3)(xx) corrected ... †11697
175.320 (b)(3) table amended ... †7206
176.170 (a)(5) table amended ... 37973, 41852, 41853
Correctly designated; (a)(5) table corrected ... 44544
(a)(5) table corrected ... 49452
(a)(5) table amended ... 59065, 62130
(b)(2) table amended ... 65150
(b)(2) table corrected ... †2393
(b)(2) table amended ... †7206
176.180 (b)(2) amended; eff. 4-20-78 ... †11698
176.300 (c) amended ... 41854
177.1010 (c)(7)(iv) corrected ... 56728
177.1020 Stay note removed; (f) added ... 48543
Technical correction ... 61254
177.1030 Stay note removed; (f) added ... 48543
Technical correction ... 61254
177.1040 Stay note removed; (f) revised ... 48543
Technical corrections ... 61254
177.1050 Stay note removed; added ... 48544
177.1210 (b)(5) Table 1 corrected ... 56728
177.1330 Introductory text corrected ... 56728

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177.1480 Stay note removed; (d) added..........48544
177.1630 (e)(4)(iii) amended..........18611
177.1810 (b) table amended..........28534
(b) and (c)(2) revised..........43621
(b) and (c)(2) technical correction..........52397
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177.2355 Added..........54533
(a) corrected..........61594
178.1010 (b)(16) revised..........37974
(b)(16) corrected..........44544
(b)(16) corrected..........†1941
178.2010 (b) amended..........49452, 59496
(b) technical correction..........61254
(b) corrected..........†1941
(b) amended..........†2874
178.3520 (a)(2)(ii) amended..........49453
178.3740 (b) table amended..........44223
180.1 (f) added..........52821
181.1 (c) added..........52821
181.22 Revised..........56728
181.23 Corrected..........56728
181.24 Corrected..........56728
181.25 Corrected..........56728
181.26 Corrected..........56728
181.27 Corrected..........56728
181.28 Corrected..........56728
181.29 Corrected..........56728
182.10 Amended..........†3705
182.70 Amended; eff. 4-20-78..........†11698
182.5017 Removed..........56728
182.5049 Removed..........56728
182.5118 Removed..........56728
182.5145 Removed..........56728
182.5273 Removed..........56728
182.5361 Removed..........56728
182.5381 Removed..........56728
182.5406 Removed..........56728
182.5411 Removed..........56728
182.5470 Removed..........56729
182.5475 Removed..........56728
182.5477 Removed..........56728
182.5590 Removed..........56728
182.5634 Removed; eff. 4-20-78..........†11699
182.5650 Removed..........56728
182.5701 Removed..........56728
182.5881 Removed..........56728
182.5915 Removed..........56728
182.5920 Removed..........56728
182.5925 Removed..........56728
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184.1339 (d) removed..........55205
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184.1555 Added..........48336
184.1634 Added; eff. 4-20-78..........†11699
184.1635 Added; eff. 4-20-78..........†11699
184.1698 Added..........†3705
186.1839 Added; ef. 4-20-78..........†11698
189.110—189.190 (Subpart C) Heading removed; (Subpart B) Heading revised..........56729
189.180 (b) revised..........56729
189.191 Added; eff. 2-15-78 and 4-15-79 in part..........†11317
189.220—189.280 (Subpart D) Heading redesignated as (Subpart C)..........56729
193.212 (a) amended..........29857
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193.235 (b) and (c) redesignated as (c) and (d) and revised; new (b) added..........58739
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193.380 (d) redesignated as (e); new (d) added..........59852
193.415 Revised..........23149

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170.17 (c) added; eff. 6-20-79..........60021
170.35 (c)(1)(vi) added; eff. 6-29-79..........60021
171.1 (k) added; eff 6-29-79..........60021
171.6 Revised; eff 6-20-79..........60021
172.372 Added..........27784
172.510 (b) amended..........14644
172.515 (b) amended..........19843
172.822 (b)(4) added..........18668
173.315 (a)(3) table amended..........54926
173.345 (c)(1)(i) corrected..........14644
173.395 Added..........54237
175.105 (c)(5) table amended..........16311, 16972, 22676

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176.170 (a)(5) table amended...45557, 49534
177.1010 (a)(3)(ii) amended.........54927
177.1350 (a)(5) added.........29287
177.1550 Revised.........44834
177.2480 (b)(1)(ii) and (e)(2) revised.........44835
177.2600 (c)(4)(iii) amended.........16972
178.2010 (b) table amended.........47723
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178.3400 (c) amended.........58557
178.3570 (a)(3) amended.........54928
180.1 (c)(4) added; eff. 6-20-79....60021
182.10 Amended.........Δ3963
182.20 Amended.........Δ3963
182.60 Amended.........47724
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182.90 Amended.........22938
182.1275 Removed.........29288
182.1973 Removed.........14644
182.1975 Removed.........14644
182.3025 Removed.........19843
182.4029 Removed.........36064
182.4037 Removed.........36064
182.4053 Removed.........36064
182.4105 Removed.........36064
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182.5634 Technical correction.... 14008
182.6807 Removed.........22938
184.1007 Added.........47724
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184.1206 Technical correction.... 14008
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184.1259 Added.........54239
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184.1634 Technical correction.... 14008
184.1635 Technical correction.... 14008
184.1807 Added.........22938
184.1973 Added.........14644
184.4560 Added.........36064
186.1025 Added.........19843
186.1275 Added.........29288
186.1807 Added.........22938
193.25 Amended.........35915
193.85 Revised.........Δ7945
193.105 Added.........22345
193.145 Added.........29558
193.235 (b) revised; (c) amenede.........Δ13475
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193 212 (a) amended.........22176
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193.235 (b) amended.........20489
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175.300 (b)(3)(xxxiii) amended...40886
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175.320 (b)(3) amended.........*6541
176.170 (a)(5) table amended...20654, 48967, 51218, *14846
(b)(2) table amended.........42678
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178.180 (b)(2) table amended...... 20654
176.300 (c) table amended.........75627
177.1390 Added.........*2843
177.1500 (b) table amended.........*2844
177.1520 (a)(3)(i) revised.........59506
(b) amended.........74817
177.1630 (e)(4)(iii) amended.........40886
(e)(4)(iii).........*6541
177.2440 Added.........34493
177.2600 (c)(4)(ix) amended.........52189
178.2010 (b) table amended...47537, 47538, 51218, 59506
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178.3400 (c) table amended.........42679
178.3690 Added.........*1018
178.3860 (b) table amended.........69649
182.60 Amended.........20656
182.70 Amended.........28323
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182.90 Amended.........*6085
182.1069 Removed.........20656
182.1091 Removed.........20657
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182.1143 Removed.........*6085
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184.1230 Added............................... *6086
184.1643 Added............................... *6086
184.1660 (d) revised............................52826
186.1551 Added...............................28323
186.1750 Added............................... *16470
186.1797 Added............................... *6086
193.15 Added....................................23212
193.20 (b) revised..............................35210
193.25 Revised.................................. 40282
193.85 (a) revised..............................35209
193.145 (a) amended.......................... 38842
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193.156 Added...................................40282
193.235 (a) amended......................... *1418
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193.325 Added...................................59232
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171.6 Amended; eff. 7-27-81........ †8952
172 Incorporation by reference approvals...................................†19660
172.230 Revised.............................. 48123
172.515 (b) amended........................22915
172.615 (a) amended.................... . 56051
172.836 (c)(15) added.....................58836
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172.840 (c)(14) added.....................58835
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172.846 Revised.............................. 51767
172.886 (d) amended........................48123
172.898 (d) revised...........................58836
173 Incorporation by reference approvals...................................†19660

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173.310 (c) table amended...79322, 85726
175 Incorporation by reference approvals...................................†19660
175.105 (c)(5) table amended...48124, 51185, 56796, 76998
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175.300 (b)(3)(xxxi) amended..... 39252
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175.360 (b) revised.........................76998
176 Incorporation by reference approvals........ ....†19660
176.170 (a)(5) amended................ 28317
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176.180 (b)(2) table amended...48124, 48125, 56052
177 Incorporation by reference approvals...................................†19660
177.1010 (a)(7) removed; (a)(8) redesignated as (a)(7)...............67321
177.1315 Added...............................39252
177.1330 Revised............................ 22916
177.1520 (b) table amended....... †16676
177.2480 (b)(1) introductory text revised; (b)(1)(iii) redesignated as (b)(1)(iv) and revised; new (b)(1)(iii) added...... 58837
177.2600 (c)(4)(viii) amended...... 67321
178 Incorporation by reference approvals...................................†19660
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178.1010 (b)(7) and (c)(5) revised...25389
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178.2010 (b) table amended........ 57711, 58837, 60423, 70444, 76999, †27, 3831, 7271, 9941, 10462
178.3130 (b) table amended...56797, 85727
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179 Incorporation by reference approvals...................................†19660
180 Incorporation by reference approvals...................................†19660
180.1 (c)(6) added; eff. 7-27-81.... †8952
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193.100 (c) revised	47143
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172 Incorporation by reference approvals	Δ3670
172.215 (b)(1) revised	Δ11835
172.280 (a) amended	Δ947
172.320 (b)(1) introductory text and (2) introductory text revised	Δ11836
172.340 Added	38072
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172.808 (b)(3) revised	57476
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172.841 Added	30081
172.846 (b) revised	Δ11837
172.860 (c)(1), (2), and (3) revised	Δ11837
172.862 (b) introductory text, (1) and (2) revised	Δ11835
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172.878 (c) table amended	Δ8764
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172.882 (a) revised	Δ11838
172.886 (b) footnote 1 revised	Δ11838
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173 Incorporation by reference approvals	Δ3670
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173.25 (a)(18) and (b)(4) added	40181
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173.160 (b)(2) and (d) revised	Δ11838
173.165 (b)(2) and (d) introductory text revised	Δ11838
173.228 Added	Δ146
173.280 (c) revised	Δ11839
173.310 (c) table amended	Δ11839
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173.340 (a)(2) amended	30493
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173.395 (d) revised	Δ11839
175 Incorporation by reference approvals	Δ3670
175.105 (c)(5) table amended	Δ1288, 9395
175.250 (b)(1), (2), and (3) revised	Δ11839
175.270 (b) introductory text and (5) introductory text revised	Δ11839
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176.170 (a)(5) table amended...... 35087
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176.180 (b)(2) table amended...... 57476
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177.1030 (b) table, (c)(2), and (d)(2) amended....................... Δ11841
177.1040 (c) footnote revised.... Δ11841
177.1050 (b) table, (c)(2) and (3), (d) introductory text and (e)(4) amended........................Δ11841
177.1200 (c) table amended.......Δ11842
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177.1360 (b) introductory text and (c) introductory text amended.................................. Δ11842
177.1390 (c)(3)(i) amended........Δ11842
177.1430 (a)(1), (2), and (3) amended.................................. Δ11842
177.1480 (b)(1)(ii) and (2) introductory text revised...............Δ11843
177.1520 (d)(1), (2)(i) and (ii) revised; (d)(5) introductory text revised and (6) amended....... Δ11843
177.1550 (d)(2) and (3) amended; (e) footnote revised................Δ11843
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177.1680 (a)(1) amended.............. 57033
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177.1820 (c)([illegible]) amended............Δ11844
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177.1980 (c)(1)(ii) amended.......Δ11845
177.2210 (b) amended..................Δ11845
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177.2470 (c)(2) amended............Δ11846
177.2480 (c)(3) and (4), and (d)(2)(i) amended..................Δ11846
177.2490 (a) introductory text amended.................................. Δ11846
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178.3480 (c) introductory text amended.................................. Δ11847
178.3530 (a) amended.................Δ11847
178.3610 (a) amended.................Δ11847
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178.3780 (b)(1), (2), and (3) amended................................. Δ11849
178.3850 (b)(3) table amended....Δ1288
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178.3910 (a)(4)(i)(*a*), (*b*), and (c) amended; (a)(4)(iii) footnote 1 revised...................................Δ11847
179 Incorporation by reference approvals.................................. Δ3670

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193.186 (d) added........ 47534
193.235 (a) revised........ 32239
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175.300 (b)(3)(xxxi) amended...41102
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175.360 (b) corrected...54430
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177.1210 (b)(5) table amended...22090
177.1315 (a) and (b) revised; (c) and (e) removed; (d) redesignated as (c)...24288
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177.1390 (a) amended; (c) introductory text, (2) and (3)(i) revised; (c)(1)(i)(A) through (E) redesignated as (c)(1)(i)(*a*) through (*e*)...49639
177.1480 (b)(2) corrected...16775
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177.1630 (e)(4)(v) added...53346
177.1820 (b) table amended...14698
177.2440 Introductory text and (a) revised...38885
177.2480 (b)(1) revised...51562
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